ATTACHMENT 82

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff and Counter-defendant, vs. INTUITIVE SURGICAL, INC., Defendant and Counterclaimant.	Case No.: 3:21-cv-03496-VC

Expert Report of Dr. Robert D. Howe
OUTSIDE COUNSEL ONLY—SUBJECT TO PROTECTIVE ORDER

January 18, 2023

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I. Qualifications

1. I received a Ph.D. in Mechanical Engineering from Stanford University in 1990, a Masters in Mechanical Engineering from Stanford University in 1985, and a Bachelor degree in Physics from Reed College in 1979. Prior to attending graduate school I worked in Silicon Valley as an electronics engineer, designing analog and digital electronics. Since receiving my doctorate, I have devoted my professional career to the research, design, development, study, and teaching of numerous aspects of mechanical and bioengineering.

2. I am currently the Abbott and James Lawrence Professor of Engineering at the Harvard Paulson School of Engineering and Applied Sciences. I serve as the founding co-chair of the Harvard MS/MBA degree program, a joint effort of Harvard's engineering and business schools aimed at training leaders in commercialization of technology. I am also a core faculty member of the Harvard-MIT Division of Health Sciences and Technology, a premier biomedical graduate training program. In 1990, I founded the Harvard BioRobotics Laboratory, which investigates the roles of sensing and mechanical design and motor control in both humans and robots. I have taught numerous courses at Harvard ranging from entry-level mechanical engineering courses to graduate-level robotics and bioengineering seminars. In 2007, I was elected Fellow of the American Institute for Medical and Biological Engineering, and in 2012, I was elected Fellow of the Institute of Electrical and Electronic Engineers. I have held visiting and adjunct scientist or professor positions at the Massachusetts Institute of Technology, Stanford University, Tufts University, and several foreign institutes and universities.

3. I am a named inventor on nine patents involving robotic and medical device technology and am the author or co-author of over 200 peer-reviewed technical publications.

4. I provided expert testimony in *Rebotix Repair LLC v. Intuitive Surgical, Inc.* and *Restore Robotics LLC and Restore Robotics Repair v. Intuitive Surgical, Inc.* In both cases, I

submitted expert reports on: (1) differences between EndoWrist instruments and traditional laparoscopic instruments; (2) Intuitive's design control and risk management processes for EndoWrist instruments; (3) Intuitive's life testing of EndoWrist instruments; (4) the "EndoWrist Service Procedure" employed by Rebotix and Restore, respectively; (5) Rebotix's risk management activities; and (6) Rebotix's life testing. In *Restore Robotics*, my expert report also discussed Restore's "service" procedures for da Vinci surgical systems. I also provided a supplemental expert report in *Restore Robotics* discussing the FDA's recent clearance of Iconocare Health's 510(k) application, which permits Iconocare to market a remanufactured S/Si 8mm Monopolar Curved Scissor instrument reset one time with ten additional lives (for a total of up to 19).

5. I previously submitted an expert report in this case on: (1) differences between EndoWrist instruments and traditional laparoscopic instruments; (2) the "EndoWrist Service Procedure" employed by Rebotix on behalf of SIS; (3) SIS's assumption that Rebotix's service procedure is safe and reliable; (4) SIS's reliance on Rebotix's risk management and life testing; and (5) Rebotix's risk management activities and life testing. Those opinions are incorporated by reference into this Report.

6. My education and experience in these fields are set forth in detail in my attached curriculum vitae, attached as Appendix A of this Report, which includes a list of publications authored in the previous 10 years and a list of all other cases in which I have testified or been deposed in the past four years.

II. Assignment

7. I have been retained by counsel from the law firm Skadden, Arps, Slate, Meagher & Flom LLP on behalf of its client, Intuitive Surgical, Inc. ("Intuitive"), concerning a dispute between Intuitive and Surgical Instrument Service Company, Inc. ("SIS"). In particular, I have

been asked to provide opinions on the safety and reliability of the services performed by third parties on EndoWrists and the Intuitive systems. This includes responding to certain opinions offered in the expert reports of Richard Bero, Russell Lamb, Amandeep Mahal, and Philip Phillips, provided in support of Plaintiff's claims. My general understanding of the dispute as it relates to my Report and analysis is as follows.

8. Intuitive designs, manufactures, and markets the da Vinci robotic-assisted surgical system ("da Vinci"), along with its associated instruments, including EndoWrist instruments, for use in minimally invasive surgery. Certain da Vinci instruments, such as EndoWrist instruments, incorporate a usage limit on the number of procedures that can be performed, after which the instrument must be replaced. As Intuitive explains in its Answer and Counterclaims, the usage limits "are determined through a rigorous process involving substantial scientific testing and analysis"[1] to ensure EndoWrist instruments are "safe, reliable and efficacious."[2] And as described further below, Intuitive's usage limits "are critical for patient safety, designed in compliance with FDA regulations, requirements and publications, consistent with applicable industry standards as well as EndoWrist labeling and amply supported and validated by scientific testing."[3]

9. SIS is a third party that has offered certain services in connection with da Vinci robotic-assisted surgical systems, including for certain EndoWrist instruments that can be used with the S and Si da Vinci Surgical systems.[4] SIS facilitated for its customers a "reset service"

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[1] Defendant Intuitive Surgical, Inc.'s Counterclaims, ¶ 29 (filed Dec. 14, 2021).

[2] *Id.* ¶ 27.

[3] *Id.* ¶ 13.

[4] EndoWrist Instruments that can be used with Intuitive's S and Si da Vinci systems are often referred to as S and Si instruments. In addition, most of Intuitive's internal engineering and

that bypasses the original usage limits of EndoWrist instruments to enable end-users to keep using the EndoWrist instruments beyond those built-in limits. SIS did not perform the reset process itself, but instead relied entirely on another third party, Rebotix Repair LLC ("Rebotix").[5] SIS simply facilitated EndoWrist instrument resetting for its customers by Rebotix.[6] Rebotix is able to bypass Intuitive's usage counter by inserting a "Rebotix Interceptor" into EndoWrist instruments, which according to Rebotix, resets the usage counter. In its Complaint, SIS alleges that "[a]fter service by SIS, the surgical device or instrument is returned to the customer for its original intended use . . . and the surgical device or instrument is returned to its original safety and effectiveness."[7] But as Intuitive explains in its Counterclaims, Rebotix's insertion of the Interceptor "override[s] a fundamental feature of EndoWrists, significantly changing their intended use and their performance and safety specifications."[8] As SIS explained in deposition, installing the Interceptor chip in an EndoWrist was done to "add 10 additional lives to that device."[9] In addition, SIS testified that it did not do anything to confirm that

technical documents refer to the S and Si systems as the IS2000 and IS3000 systems and refer to the EndoWrist instruments as IS2000 and IS3000 instruments, respectively.

[5] Oct. 27, 2022 Keith Johnson 30(b)(6) Tr. at 33:22-34:2 ("[Q.] My question was: Did SIS ever actually perform the [EndoWrist repair] service in-house. A. No. Q. So for all of the EndoWrist repairs that SIS facilitated, those repairs were actually performed by Rebotix; correct? . . . A. Correct."); *see also* Nov. 1, 2022 Greg Posdal 30(b)(6) Tr. at 22:10-12 ("Q. SIS does not itself perform the resetting process; correct? A. It -- that is correct.").

[6] Oct. 27, 2022 Keith Johnson 30(b)(6) Tr. at 33:25-34:4.

[7] SIS Complaint, ¶ 33 (filed May 10, 2021).

[8] Defendant Intuitive Surgical, Inc.'s Counterclaims, ¶ 48 (filed Dec. 14, 2021).

[9] Oct. 27, 2022 Keith Johnson 30(b)(6) Tr. at 22:10-11.

insertion of the Interceptor "does not alter the intended use, method of use, functionality or performance of the device in any way,"[10] despite making such representations.[11]

10. Another third party, Restore Robotics LLC (collectively with its related entity Restore Robotics Repairs LLC, "Restore") also offered certain services in connection with da Vinci robotic-assisted surgical systems, including for EndoWrist instruments that can be used with the S and Si da Vinci Surgical systems. Like SIS, Restore offered a "service" that bypassed the original usage limits of EndoWrist instruments, utilizing the Interceptor technology developed by Rebotix, so that end-users could continue using EndoWrist instruments beyond those built-in limits. In addition to bypassing the usage limits on EndoWrist instruments, Restore also offered to customers servicing of the da Vinci robotic surgical system. I understand that SIS currently has a business relationship with Restore and is working with Restore to develop a "repair" program for Xi EndoWrist instruments, which I understand to involve resetting the usage counter on those instruments.[12]

11. Another third party, Iconocare Health, recently received clearance from the FDA for a different EndoWrist remanufacturing process than that employed by Rebotix and Restore. Specifically, on September 30, 2022, the FDA cleared Iconocare Health's 510(k) application, which permits Iconocare to market a remanufactured S/Si 8mm Monopolar Curved Scissor instrument reset one time with ten additional lives (for a total of up to 19),[13] using a remanufacturing process referred to in this Report as the "Iconocare Process."

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[10] Nov. 1, 2022 Greg Posdal 30(b)(6) Tr. at 66:9-14 ("Q. SIS did not do anything to confirm that it was accurate, that 'The repair of da Vinci EndoWrist does not alter the intended use, method of use, functionality or performance of the device in any way'; correct? A. That is correct.").

[11] *See* Def.'s Ex. 136, SIS095115-095139 at SIS095124.

[12] Oct. 27, 2022 Keith Johnson 30(b)(6) Tr. at 40:8–21, 43:6–24.

[13] Restore-00089490 at Restore-00089492–93 ("If the Current Available Uses on an instrument is less than 1, the PCB will not be able to be installed and the instrument must be set aside for

12. I was asked to review the record information in this matter regarding Intuitive's mechanical design of the EndoWrist instruments and the scientific testing performed to validate the EndoWrist usage limits. I was also asked to review the available information regarding the development of the Rebotix Interceptor, the installation of the Rebotix Interceptor, and any testing (or lack of testing) that Restore, Rebotix, or SIS performed to determine whether bypassing the EndoWrist's usage limits was mechanically viable or safe and reliable for patient use. Finally, I was asked to review information regarding the Iconocare Process, and assess any differences between the Restore/Rebotix Process and the Iconocare Process, as well as the risk management and life data supporting each process.

13. What follows is a Report on my findings after a review of the relevant materials, which were identified through an examination of documents produced in the litigation, SIS's Complaint (ECF No. 1) ("SIS Complaint"), Defendant Intuitive Surgical, Inc.'s Answer, Affirmative Defense and Counterclaims (ECF No. 75), a review of testimony provided by witnesses at deposition, and a review of SIS's written discovery responses. A list of materials I considered in connection with this matter is attached as Appendix B of this Report.

14. I am being compensated for my work at the rate of $600 per hour. My compensation is in no way dependent on the outcome of this matter. Additional time required for trial testimony or deposition will also be billed at the rate of $600. I was supported in this matter by a postdoctoral research associate in the Harvard Paulson School of Engineering and Applied Sciences, Dr. Richard Nuckols, who was compensated for his work at the rate of $125 per hour.

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disposition. If the Current Available uses on an OEM instrument is greater than (or equal to) 1, the instrument can proceed with service process.").

III. Summary of Opinions

15. It is my opinion that there are significant differences between EndoWrist instruments and traditional laparoscopic instruments, and that these differences contribute to EndoWrist instruments having a shorter useful life than traditional laparoscopic instruments. Unlike traditional laparoscopic instruments, EndoWrists have a set of mechanical joints (or "wrists") at their distal end[14] which permit three degrees of freedom of movement (as compared to one or at most two degrees of freedom in typical traditional laparoscopic instruments). These additional degrees of movement in EndoWrists are made possible by the use of cables and pulleys within the instrument. While the cable and pulley mechanisms utilized by EndoWrist instruments permit additional degrees of movement and dexterity, they are less durable and more prone to mechanical failure over an extended period of use than the drive rods typically utilized in traditional laparoscopic instruments. There is thus a tradeoff whereby EndoWrist instruments permit increased dexterity and freedom of motion but fewer uses as compared to traditional laparoscopic instruments.

16. It is my opinion that Intuitive maintains rigorous design control and risk management processes which illuminate, and allow Intuitive to account for, the various risks or potential failure modes associated with the EndoWrist instruments. Intuitive's comprehensive design control processes allow Intuitive to design instruments so as to support reliable and consistent performance over a prescribed number of uses.

[14] The distal end, as the term is used regarding EndoWrist instruments, is the portion of the instrument that interacts with the patient to perform a function during a surgical procedure. The other end, referred to as the proximal end, is the portion of the instrument that connects to the da Vinci surgical system.

17. It is my opinion that Intuitive's rigorous testing of its EndoWrist instruments adequately reflects the stresses and forces that instruments are subjected to during clinical use and demonstrates that instruments can only be reliably used a limited number of times. Both Intuitive's life testing and actual, clinical results demonstrate that EndoWrist instruments experience significant wear and tear during their prescribed useful life.

18. It is my opinion that although Rebotix, Restore, and SIS refer to the "reset" services as a "repair,"[15] Rebotix simply devised a method that intercepts communication between the robot and the instrument in order to circumvent the usage limits implemented in each EndoWrist instrument, without adequately addressing the effects of wear and tear that accrue during instrument usage.

19. [redacted]

[15] Def.'s Ex. 136, SIS095115-095139, at SIS095120.

[16] *See* REBOTIX162404 (described *infra* § VI.A).

[17] *See* Restore-00001538.

20. It is my opinion that Rebotix's risk management activities with respect to extending the lives of EndoWrist instruments are inadequate. Rebotix's risk management activities with respect to extending the life of the EndoWrist instruments assume that the Rebotix servicing procedure is adequate to restore the instruments to equivalent specifications to new instruments, but do not consider the deleterious effects of previous surgical uses and sterilization procedures, which have been clearly shown to decrease reliability. In addition, they do not adequately address the risks of mechanical failure associated with using an EndoWrist instrument beyond the prescribed usage limit.

21. It is my opinion that Rebotix's life testing fails to adequately simulate the stresses and forces that instruments are subjected to during clinical use and therefore cannot reliably be said to validate the use of the EndoWrist instruments for uses beyond the prescribed usage limit.

22. It is my opinion that Restore and SIS relied entirely on Rebotix's risk management activities and life testing, and that the limited information available to them was not sufficient to determine whether the instrument was safe or reliable.

23. It is my opinion that Intuitive's position that it could potentially develop robust EndoWrist refurbishment procedures does not mean that Rebotix's resetting procedures were adequate.

24. It is my opinion that there are significant differences between the Rebotix Process for remanufacturing S/Si EndoWrist instruments and the Iconocare Process for remanufacturing the S/Si 8mm Monopolar Curved Scissor EndoWrist, and the Iconocare Process is likely to produce safer and more reliably-remanufactured instruments than the Rebotix Process.

25. It is my opinion that the risk management and life data submitted to the FDA for the Iconocare Process is significantly more robust than the risk management and life testing data Rebotix had access to in connection with the Rebotix Process.

26. It is my opinion that, while even a single EndoWrist reset introduces safety risks, there are significantly greater safety risks created by resetting an EndoWrist usage counter multiple times (as Restore and Rebotix claimed they could do with their processes) than by resetting the usage counter once (as called for by the Iconocare Process).

27. Discovery is ongoing in this matter, and I reserve the right to amend or supplement my opinions and findings as additional material becomes available.

IV. The Intuitive EndoWrist Instrument and the Interceptor

A. Overview of Intuitive S/Si EndoWrist Instruments

28. EndoWrist instruments are designed for use in conjunction with the da Vinci surgical robot system. I first became aware of the EndoWrist instrument design through conversations with Dr. Ken Salisbury and Akhil Madhani, his doctoral student at MIT, soon after they invented these instruments in the mid-1990's. After their invention, I have had many EndoWrist instruments in my lab, which we analyzed as part of our research efforts on new surgical instrumentation. I have also had many opportunities to operate various models of the da Vinci robot, including an extended collaboration with surgeons at Boston Children's Hospital, where they had a robot dedicated to training and research that afforded me and my research group opportunities to perform experiments on sensing and control using the robot.

29. EndoWrist instruments are endoscopic instruments that access tissues within the patient's body through small incisions in order to minimize damage to healthy tissue. In contrast to conventional manually-driven endoscopic (laparoscopic) instruments, EndoWrist instruments have a set of mechanical joints located at the distal end. *See* Figure 1. This allows the surgeon to

freely orient the end effector to perform dexterous maneuvers, which greatly enhances the ability to effectively and efficiently carry out minimally invasive surgical procedures.[18]

30. To provide the additional degrees of freedom at the surgical site compared to traditional laparoscopic instruments, EndoWrist instruments use a sophisticated cable drive mechanism. This innovative system was the subject of several issued US and international patents.[19] Four input pulleys on the proximal end of the instrument mate with motor drives in the surgical robot. These pulleys are connected to internal cables that control roll of the instrument shaft, yaw and pitch of the instrument wrist, and open/close of the end effector. These cables pass over idler pulleys, then through the elongated instrument shaft to the wrist, where they are routed over a series of pulleys to produce the intended motion. Inside the central length of the shaft, the cables are crimped onto rods to reduce the effects of cable stretch, but the cables wrap around pulleys in both the proximal and distal ends of the instrument. In addition to allowing the required degrees of freedom to fit within the constrained shaft diameter, the use of cables also enables a large range of motion in each degree of freedom.

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[18] *See* REBOTIX152284 at REBOTIX152297 (2014 Instrument and Accessories User Manual (S/Si instruments)). My descriptions of the features of EndoWrist instruments pertain to S and Si EndoWrist instruments, except for descriptions of the Xi instruments as specifically noted below.

[19] *See, e.g.*, US Patent Nos. 5,797,900 ("Wrist Mechanism for Surgical Instrument for Performing Minimally Invasive Surgery with Enhance Dexterity and Sensitivity") and 6,991,627 ("Articulated Surgical Instrument for Performing Minimally Invasive Surgery with Enhanced Dexterity and Sensitivity").

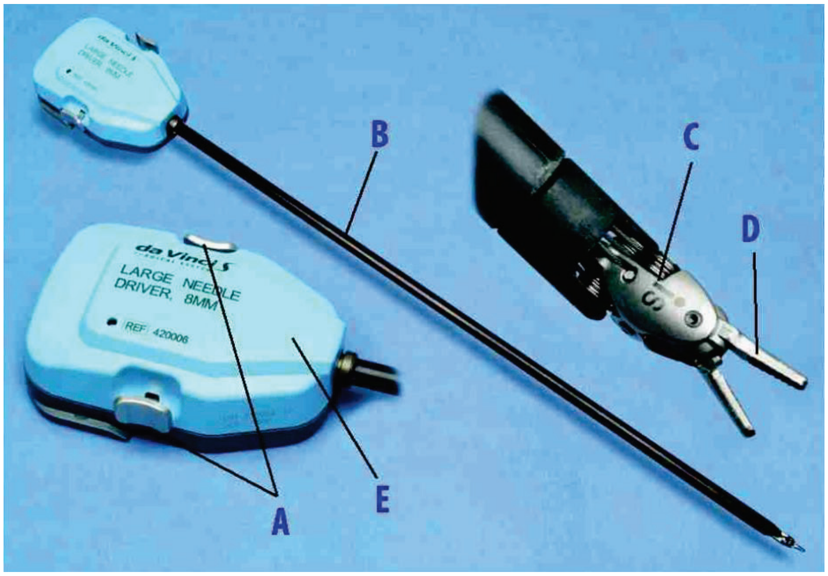

Figure 1.[20]

31. An essential part of the specifications for the EndoWrist instruments is a limitation on the number of times each instrument can be used for surgical procedures.[21] In S and Si instruments, the limitation is implemented through an integrated circuit that keeps track of the number of times the instrument is used in a surgical procedure by a da Vinci robot. This chip, a Maxim/Dallas Semiconductor DS2505 (sometimes referred to as the "Dallas chip") resides on a small printed circuit board in the proximal housing of each instrument. It is an add-only memory that communicates with the robot over a one-wire bus, where additional data can be programmed

[20] REBOTIX152284 at REBOTIX152297 (Intuitive 2014 Instrument and Accessories User Manual (S/Si instruments)). The figure above demonstrates that EndoWrist Instruments consist of five main components: the Release Levers (A); the Instrument Shaft (B); the Wrist (C); the Tip or End Effector (D); and the Instrument Housing (E). REBOTIX152284 at REBOTIX152297.

[21] As described further below, the specifications for EndoWrist instruments are detailed in a series of documents, which include Architectural Requirement Documents ("ARDs") and Functional Requirements Documents ("FRDs"), among others. The ARD for the IS1200, IS2000 and IS3000 Instruments provide that the instruments "shall be programmed with the number of uses as specified in the individual Instrument Functional Requirements." Intuitive-00538487 at Intuitive-00538496. The FRDs contain the specific requirements for individual instruments and set out the maximum number of times each type of instrument may be used. *See* Intuitive-00539807.

into EPROM without disturbing existing data, and each memory page can be permanently write-protected to prevent tampering. In addition, each chip has a unique factory-set serial number.[22] These features provide a secure means for keeping track of the number of uses. During manufacturing, the DS2505 chip is programmed with the total number of allowed uses; for most S and Si EndoWrist instruments, this usage limit is ten surgical procedures.[23] When an instrument is connected to a da Vinci robot, the robot's controllers communicate with the chip over the one-wire bus via a pogo pin connector in the proximal housing. The robot queries the chip for stored information, including the number of previous uses. If the uses have been decremented to zero, the robot will not activate the instrument. If the robot commences with use of the instrument for the surgical procedure, the number of uses stored in the chip is decremented by one.[24] In X/Xi instruments, the usage limitation is implemented through an RFID chip that communicates the use counter information and other data from the EndoWrist to the da Vinci system itself.[25]

B. Differences Between Intuitive EndoWrist Instruments and Traditional Laparoscopic Instruments

32. SIS alleges in its Complaint that EndoWrist instruments are "substantially identical to similar instruments used in traditional surgeries."[26] SIS also alleges that "EndoWrist instruments are suitable for many more uses" than their original use limits.[27] In deposition, SIS

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[22] *See* DS2505 Dallas Semiconductor data sheet, available at: https://datasheets.maximintegrated.com/en/ds/DS2505.pdf; *see also* Intuitive-00538487 at Intuitive-00538496 (describing Dallas Chip Interface Requirements for EndoWrist instruments).

[23] *See* Intuitive-00539807 (FRD) (setting out usage limits).

[24] *See, e.g.*, BB000011.

[25] Nov. 8, 2022 Grant Duque 30(b)(6) Tr. at 22:5–23:17; Nov. 4, 2022 Sharathchandra Somayaji Tr. at 108:18–109:22.

[26] SIS Complaint, ¶ 27 (filed May 10, 2021).

[27] *Id.* ¶ 35.

testified that EndoWrists are "very simple laparoscopic instrument[s]."[28] Contrary to claims made by SIS, there are a number of features that are unique to EndoWrist instruments as compared to those in traditional laparoscopic instruments. Plaintiff's experts assert that the use limits on EndoWrists do "not provide a surgeon any practical, relevant information about the instrument's actual usage,"[29] and that Intuitive was incorrect in determining that "it is unsafe to use EndoWrist surgical instruments more than the maximum number of times" set with the usage limitations.[30] I disagree.

33. Traditional endoscopic instruments differ in essential ways from EndoWrist instruments. I have observed the use of traditional endoscopic instruments in dozens of laparoscopic and thoracoscopic surgical procedures, and my lab has analyzed their design and function as part of our own efforts to develop minimally invasive surgical instrumentation. Both traditional endoscopic and EndoWrist instruments have an elongated shaft to enable surgeons to work through a small incision. However, both the proximal and distal ends of EndoWrist instruments are significantly different than traditional endoscopic instruments, as is the mechanical connection between the ends. At the proximal end, traditional instruments have handles (typically a pair of levers or finger loops), which surgeons hold in their hands to apply forces and motions to the instrument and to open and close an end effector like scissor blades or forceps jaws (typical examples are shown in Figure 2). In contrast, EndoWrist instruments connect to a set of motor drives through four pulleys. *See* Figure 3.

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[28] Oct. 27, 2022 Keith Johnson 30(b)(6) Tr. at 24:20-21, 26:5-9.

[29] Expert Report of Amandeep Mahal (Dec. 1, 2022) ("Mahal Rep."), ¶ 65.

[30] Expert Report of Russell Lamb (Dec. 2, 2022) ("Lamb Rep."), ¶ 130.

34. The motor interface of an EndoWrist instrument introduces a number of constraints and potential failure modes to the instrument design that are not present in manual instruments. Examples of failures identified and considered by Intuitive engineers in designing the EndoWrist instruments include the possibility that the pins (or "dogs") on the input pulleys would slip or shear off, potentially resulting in loss of control of the instrument.[31] Similarly, the bearings that enable low-friction motion of the input pulleys and shafts can fail, potentially resulting in loss of instrument functionality and/or having the bearings or their fragments fall into the patient.[32] There are no analogous parts to these two examples in conventional endoscopic surgical instruments. Additional examples of potential failures that pertain to the motor interface of EndoWrist instruments are detailed by Intuitive through their design control and risk assessment process.[33]

[31] *See, e.g.*, Intuitive-00538994 at Tab 10, Rows 17-18.

[32] *See, e.g.*, *id.* at Tab 11, Row 11.

[33] *See generally id.*

Figure 2.[34]

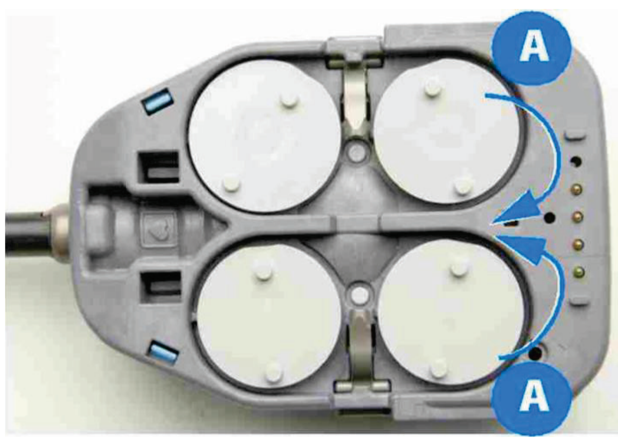

Figure 3.[35]

35. EndoWrist instruments have unique capabilities that are not available with conventional endoscopic instruments. In particular, the wrist mechanism provides three degrees of freedom at the end of the instrument, often referred to as wrist yaw, wrist pitch, and grip. This contrasts with conventional endoscopic instruments that typically have one or at most two

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[34] "Access and instruments product catalog" Medtronic, 2020, available at: https://www.medtronic.com/content/dam/covidien/library/us/en/product/hand-instruments-and-ligation/access-instrumentation-products-catalog.pdf.

[35] REBOTIX152284 at REBOTIX152360.

degrees of freedom. This provides the dexterity that allows surgeons using the da Vinci robot to perform some minimally invasive surgical procedures that are difficult or impossible to perform with conventional endoscopic instruments. While some manual instrument designs have attempted to provide additional degrees of freedom at the distal end, these have proved difficult to control in a dexterous manner; typically, an extra degree of freedom in tip orientation is manually set to a specific angle and left unchanged during subsequent maneuvers. The combination of the difficulty of control of additional degrees of freedom as well as their increased costs means that traditional endoscopic instruments do not provide the motion capabilities that EndoWrist instruments deliver. In contrast, the relative simplicity of conventional endoscopic instruments means that they can use much simpler, more robust, and less expensive drive mechanisms to fit in the constraints of shaft diameter. By far the most common design uses push-pull drive rods that pass through the instrument shaft to operate the distal degree(s) of freedom. These mechanisms are simple to design and are robust because they operate in simple loading conditions that are accurate to model during design and robust during operation, in contrast to the cable drives in EndoWrist instruments. As a result, traditional instruments are more resilient to fatigue, corrosion, and wear.[36]

36. Because the EndoWrist instruments are driven by motors under computer control, they are also subject to high forces due to collisions that are not present for manual instruments. When a surgeon uses the control inputs to command an instrument to move along a path that intersects with another instrument, the ensuing collision can prevent the instrument from going to the commanded location. The instrument controllers can then generate high motor

[36] Richard G. Budynas and J. Keith Nisbett, Shigley's Mechanical Engineering Design, Ninth Edition, McGraw- Hill, New York, 2008, Chapters 3-5.

forces in an attempt to move the instrument as commanded, resulting in high forces applied to the instrument, particularly the wrist. This type of interaction is not present for manual laparoscopic instruments, where instrument motions are directly generated by the surgeon's hands and collisions result in far lower forces.

37. Unlike drive rods, cable drives (often alternatively referred to as "wire rope drives") are more complex to design, particularly for high reliability across product life. Designers of wire cable or rope drives frequently focus on wear and fatigue issues. For example, a leading textbook on mechanical design elucidates these issues in the context of the interaction between the rope and the pulleys (or "sheaves") over which it passes:

> Once you have made a tentative selection of a rope based upon static strength, the next consideration is to ensure that the wear life of the rope and the sheave or sheaves meets certain requirements. When a loaded rope is bent over a sheave, the rope stretches like a spring, rubs against the sheave, and causes wear of both the rope and the sheave . . . The allowable pressures given in Table 17-26 are to be used only as a rough guide; they may not prevent a fatigue failure or severe wear. They are presented here because they represent past practice and furnish a starting point in design. . . . In view of the fact that the life of wire rope used over sheaves is only finite, it is extremely important that the designer specify and insist that periodic inspection, lubrication, and maintenance procedures be carried out during the life of the rope.[37]

38. The EndoWrist design is particularly challenging because of its small size and multiple degrees of freedom. *See* Figure 4.

[37] Richard G. Budynas and J. Keith Nisbett, Shigley's Mechanical Engineering Design, Ninth Edition, McGraw- Hill, New York, 2008, Chapter 7, pp. 919-921.

Photo Identification of Endowrists

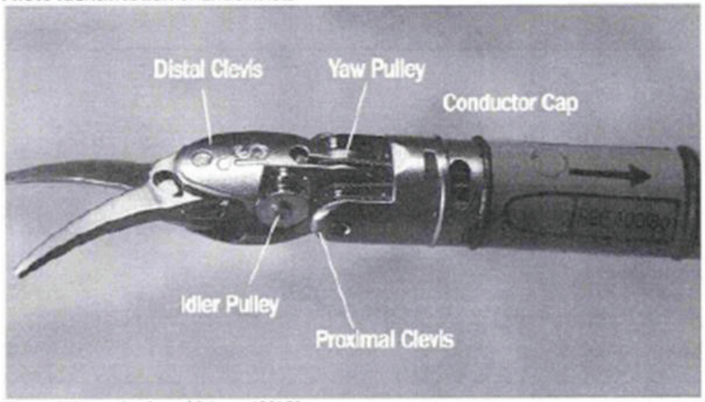

Figure 13 Monopolar Curved Scissors 420179

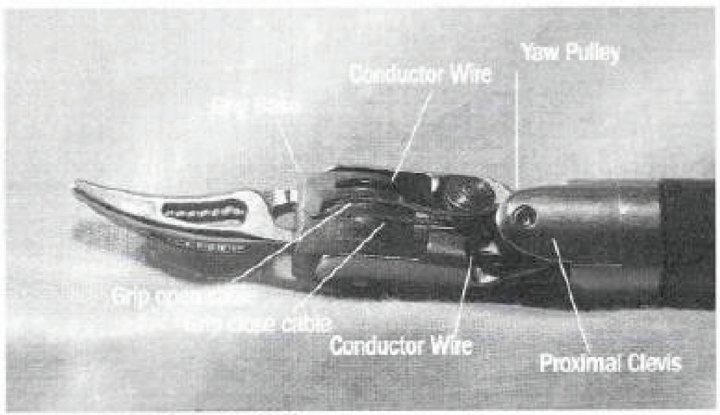

Figure 14 Maryland Bipolar Forceps 420172

Version vs Cause

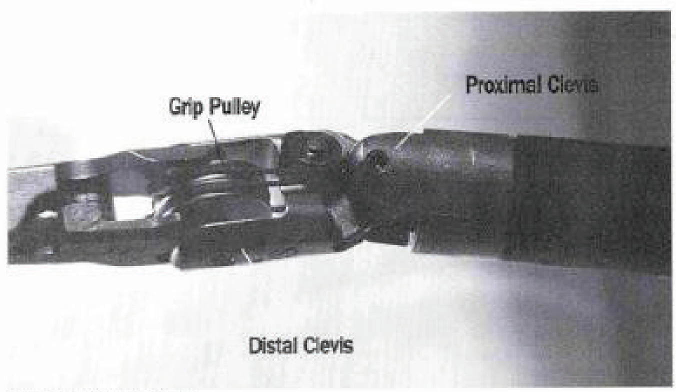

Figure 15 Prograsp Endowrist

Figure 4.[38]

[38] REBOTIX090153 at REBOTIX090226-227.

The result is that the cables pass over multiple pulleys in alternating directions. This is known to reduce the life of the cables:

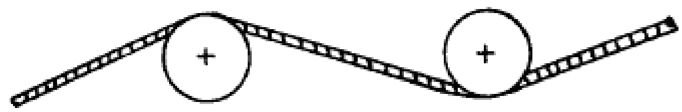

Figure 4-8. Reverse Bend

> To maximize the service life of a wire rope, it should be reeved (or threaded) through a block and tackle system with a minimum number of sheaves and the fewest possible reverse bends. Reverse bends, as shown in Figure 4-8, occur when the rope bends over a sheave in one direction, then under another in the opposite direction within a distance short enough so that a section of the rope traverses both sheaves. Bending fatigue due to this condition will reduce life to half of that experienced with only single-direction bends.[39]

39. The cleaning and sterilization cycles to which EndoWrist instruments are repeatedly subjected are particularly detrimental to continuing reliable operation. Intuitive documents describe the impact on reliability of these reprocessing cycles. For example:

> Ideally, the number of instrument uses is equal to its number of reprocessing cycles. However, depending on the practices of a hospital, instruments may undergo more reprocessing cycles than they do uses. Number of uses can be different from the number of reprocessing cycles when an instrument is brought into a sterile field, but is not put on the system and used by the surgeon. The instrument would still need to be reprocessed because it became contaminated by the surgical field, but, since the system-instrument interaction is what deducts the number of instrument lives, the number of uses remaining would remain unchanged. Current reliability testing accounts for these additional reprocessing cycles by testing to 5 additional reprocessing cycles to the

[39] U.S. Navy Wire-Rope Handbook, Vol. 1, p. 4-11.

> Weibull analysis. When the number of reprocessing cycles far outnumber the number of uses, early failures can occur.[40]

40. The corrosion that results from reprocessing is well-known to degrade wire rope drives:

> Corrosion accelerates wire-rope deterioration. It reduces rope metallic area, limits flexibility, and leads to uneven wire surfaces that may cause damage to equipment and internal damage to the rope. Corrosion within a wire rope is almost impossible to detect visually, which makes it extremely difficult to determine the true condition of a corroded rope.[41]

41. Plaintiff's reliance on Intuitive's premarket 510(k) notifications to suggest equivalence between traditional endoscopic instruments and EndoWrist instruments[42] is misplaced. As explained in detail above, the internal drive mechanisms of EndoWrists and traditional instruments are very different. Thus, although they are in many external and functional ways similar to traditional instruments, the cable drive system is significantly different from traditional laparoscopic instruments and does not allow for unlimited, reliable surgical uses.

42. Intuitive designs take these principles into account. To account for potential fatigue and wear failure, the designs are life tested and are limited to a defined number of procedures that are consistent with the reliability demonstrated in these tests. The need for these precautions is clear from the observed life test failures and RMA returned instrument failures.[43]

43. Plaintiff compares Intuitive's use limits with instruments used with TransEnterix's Senhance robotic system.[44] This is not a meaningful comparison because the cited robotic instruments do not have the same functionality or capabilities as EndoWrist

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[40] Intuitive-00004692 at Intuitive-00004699-700.

[41] U.S. Navy Wire-Rope Handbook, Vol. 1, pp. 3-15–3-16.

[42] *See, e.g.*, Compl. ¶ 27.

[43] *See generally* Intuitive-00004692.

[44] *See, e.g.*, Lamb Rep. ¶ 141.

instruments. Almost all Asensus Senhance instruments do not have wrists;[45] this robot platform is designed to perform procedures that can be accomplished with conventional laparoscopic instruments, which, as explained above, have much lower dexterity than the da Vinci robot.[46] The three instruments with wrists listed in the Asensus Senhance catalog have only a single direction of articulation at the wrist (as opposed to the two directions on EndoWrists), and that wrist portion is a single-use disposable.[47] Asensus does not offer a wristed instrument with unlimited uses.[48]

44. Similarly, Medrobotics' Flex robot instruments do not have wrists.[49] The instruments are not powered, and all motions of the instrument tips are generated by motions of the surgeon's hands on the instrument control handles.[50] Because these instruments are constrained to fit through the working channel of a flexible endoscope robot, they do not have rigid shafts, and they have a greatly restricted range of motion compared to EndoWrist

[45] Senhance Surgical System EMEA Product Catalog, January 2020.

[46] *See* Senhance.com/indications (explaining that "The Senhance® Surgical System is intended to assist in the accurate control of laparoscopic instruments . . . in general laparoscopic surgical procedures and laparoscopic gynecological surgery").

[47] Senhance Surgical System EMEA Product Catalog, January 2020 at 7.

[48] *Id.*

[49] *See* "Expanding the Reach of Surgery," Medrobotics "Flex" brochure, available at: https://www.easmed.com/main/wp-content/uploads/BROCHURE-Medrobotics-Transanaleasmed.pdf; *see also* "Flex Robotic System Technology: How it Works," available at: https://web.archive.org/web/20200815134035/https://medrobotics.com/gateway/technology/; "Flexible 'open architecture' instrumentation," available at: https://web.archive.org/web/20200923215331/https://medrobotics.com/gateway/instruments/.

[50] *See* "Flex Robotic System Technology: How it Works," available at: https://web.archive.org/web/20200815134035/https://medrobotics.com/gateway/technology/.

instruments.[51] Medrobotics does not offer powered or wristed instruments, or instruments with dexterity comparable to the EndoWrist instruments.[52]

45. In addition to the differences between EndoWrist instruments and traditional laparoscopic instruments highlighted above, EndoWrist instruments require calibration to achieve specified performance. In particular, individual drive cable assemblies are pre-tensioned to specific values in a way that counteracts the anticipated cable-stretch over the life of the instrument.[53] Cable tensioning protocols require test fixtures, torque measurement instruments, and accurate execution of a multi-step protocol.[54] This complicated process is not used for traditional instruments that do not require similar calibration. In this way, I would not expect EndoWrist instruments and traditional instruments to have the same service life.

C. Overview of Interceptor Technology

46. [redacted]

[51] *See* "Expanding the Reach of Surgery," Medrobotics brochure, available at: https://www.easmed.com/main/wp-content/uploads/BROCHURE-Medrobotics-Transanaleasmed.pdf.

[52] Furthermore, although Asensus' and Medrobotics' Flex robots may not specify a usage limit, their usage and durability in the field is not well understood as they have not yet been on the market nearly as long or as widely adopted as Intuitive's EndoWrist instruments.

[53] *See* Intuitive-00537574 at Intuitive-00537575.

[54] *See* Intuitive-00705141 (Intuitive Manufacturing Process Instructions (MPI) Cable Tensioning, 838012).

[redacted][55] [redacted].[56]

47. [redacted][57] [redacted][58] [redacted][59]

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55 [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Figure 5.[60]

48. The Interceptor interposes a Complex Programmable Logic Device (CPLD) between the DS2505 and the one-wire bus interface to the robot host. This programmable processor chip passes most communications unchanged between the robot host and the DS2505, excepting, in particular, queries on the number of surgical uses of the instrument. When the CPLD detects usage data requests, it substitutes an altered number of uses to allow the instrument to exceed the original limit. For example, Rebotix may facilitate the addition of ten more uses following installation of the Interceptor. The CPLD then intercepts robot host communication that reads or writes usage counts, and substitutes the altered number, starting with the value set during the "reset" service and then decrementing it at each surgical use. This is described in Interceptor documentation:

> By default the Interceptor passes along the data from the host 1 wire bus to the DS2505 1 wire bus. The Interceptor follows the 1 wire state flow to allow it to

[60] REBOTIX100995 at REBOTIX101000.

> determine the read slots such that the Interceptor allows a bit masked version of the DS2505 data to pass to host on an un-intercepted read. On an intercepted read the Interceptor ignores the data passed to it by the DS2505 and substitutes the data to the host with its own data . . . Finally the bus controller which handles the bus interactions to the host 1 wire bus also applies a bit wise AND mask to the data from DS2505 to the host using the data in the internal memory of the Interceptor CPLD. This AND masking provides the host with the appearance that it modified the data in the D52505 as the Interceptor stores the writes from the host.[61]

49. Software design specifications for the Interceptor spell out this functionality as well:

> [1] The Interceptor SHALL provide a factory resettable counter to allow REBOTIX to continue to use the EndoWrists once they are repaired . . .
> [4] The Interceptor SHALL allow the host to perform non-volatile writes to the Interceptor Flash Memory . . .
> [7] The Interceptor SHALL prevent the host from writing to the DS2505 . . .
> [10] For non-intercepted accesses, the Interceptor SHALL pass along bit masked data to the host from the DS2505 during a read process . . .
> [11] The Interceptor SHALL intercept/ substitute data when required . . .
> [12] The Interceptor SHALL respond to the Da Vinci Surgical System host in the same manner as the D52505 . . .[62]

V. Intuitive's Design Control, Risk Management, and Testing Processes

A. Intuitive's Design Control and Risk Management Processes

50. Intuitive employs rigorous and in-depth design control and risk management processes. Without thorough design control and risk management, surgical robots could be hazardous to both patients and surgical staff. Potential risks for instruments for the da Vinci surgical robot system include: debris falling into the surgical field or patient, increased risk of electrical arcing/burning to patient tissue, unintuitive motion of the da Vinci surgical system,

[61] *Id.* at REBOTIX101001.

[62] *Id.* at REBOTIX101002-04.

inaccurate or sluggish motions of the EndoWrist instrument, inadequate or restricted ranges of motion, and the EndoWrist instrument failing to be recognized by the da Vinci surgical system.[63] Thus, measures to control risk are necessary throughout the product development and manufacturing process. Intuitive has an extensive system in place to evaluate and manage risk. This system is in accord with standard medical device industry practice.[64]

1. Design Control

51. As described by the FDA, design controls "are an interrelated set of practices and procedures that are incorporated into the design and development process," which result in earlier detection and correction of any "deficiencies in design input requirements, and discrepancies between the proposed designs and requirements."[65]

52. Intuitive describes its design control process as "[a] systematic framework used to demonstrate that the product works and that it meets the needs of the end-user (intended use) while maintaining safety and effectiveness."[66] Design control involves: (i) design verification, which considers and tests the engineering of a product, and (ii) design validation, which considers whether the product meets the needs of the end-user.[67]

53. Within the design control framework, Intuitive's development process involves detailing what a product must do through a Market Requirements Document ("MRD") and

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[63] *See generally* Intuitive-00538913, Intuitive-00538994.

[64] *See generally* Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, available at: https://www.fda.gov/media/116573/download.

[65] *Id.* at 1 ("Design controls increase the likelihood that the design transferred to production will translate into a device that is appropriate for its intended use."). This FDA guidance on design control for medical device manufacturers is applicable to new designs as well as modifications to existing device designs. *Id.* at 2.

[66] Intuitive-00477325 at Intuitive-00477331.

[67] Intuitive-00477217 at Intuitive-00477220; *see also* Intuitive-00477325 at Intuitive-00477331-32.

Product Requirements Documents ("PRD").[68] These user and design needs are then implemented through Architectural Requirements Documents ("ARDs"), Functional Requirements Documents ("FRDs"), and lower level functional requirements and specifications.[69]

2. Risk Management

54. Risk management is part of the design process and involves "the systematic application of management policies, procedures, and practices to the tasks of identifying, analyzing, controlling, and monitoring risk."[70] As described more fully below and reflected in Figure 6, Intuitive's risk management processes are integrated into the design control process and continue through the life of a product.[71]

[68] Intuitive-00477217 at Intuitive-00477222; *see also* Intuitive-00477325 at Intuitive-00477358.

[69] Intuitive-00477217 at Intuitive-00477222; *see also* Intuitive-00477325 at Intuitive-00477364.

[70] Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, at 5, available at: https://www.fda.gov/media/116573/download.

[71] Intuitive-00477422 at Intuitive-00477424.

[redacted]

Figure 6.[72]

55. The Intuitive risk management process analyzes "risks in design and process, defines requirements to mitigate them, uses design control to trace them to tests, and analyses *[sic]* residual risk." The risk analysis incorporates both a top-down and bottom-up approach.[73]

56. From a top-down perspective, major risk management procedures and the associated documentation include a clinical risk analysis ("CRA") that is formulated early in the product development process. This procedure aims to define potential problems and mitigations

[72] Intuitive-00477422 at Intuitive-00477424.

[73] Intuitive-00477422 at Intuitive-00477424-25.

to guide product definition. The usability risk analysis ("URA") is formulated after the product is defined and considers how it might be used and misused.[74]

57. From a bottom-up perspective, Intuitive's risk management procedures include several failure mode and effects analyses ("FMEA"), including Design FMEA, ("dFMEA"), Process FMEA ("pFMEA"), and Supplier Process FMEA ("spFMEA"). FMEA analysis is performed after the product or its manufacturing process have been designed, and looks at potential failures of components and the overall system.[75] These procedures—and additional risk management documents—are coordinated with the product design process and design control documents, including definition of user needs, design inputs and outputs, and formal design reviews.[76] This process manages overall risk in the marketed products.

58. A dFMEA is the key method for defining specific risks in a medical device design. In Intuitive's dFMEA process, the device is systematically reviewed to determine the ways it could fail and the effects of a failure.[77] Each significant failure mode is assigned scores for the likelihood of occurrence, the severity of the consequences of failure, and the ability to detect the failure.[78] These scores can be combined to provide a measure of the risk priority. Important risks are then mitigated, i.e., changes to the design or the product use are implemented to reduce the risk.[79]

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[74] Intuitive-00477422 at Intuitive-00477425-26.

[75] Intuitive-00477422 at Intuitive-00477424-27.

[76] Intuitive-00477217 at Intuitive-00477220-24; *see also generally* Intuitive-00477325.

[77] *See generally* Intuitive-00477829.

[78] Intuitive-00477422 at Intuitive-00477457. *See generally* Intuitive-00477829.

[79] *See* Intuitive-00477422 at Intuitive-00477454-457; Intuitive-00477829 at Intuitive-00477844-45.

3. Design Verification and Validation

59. As previewed above, a key aspect of the design control and risk management process is design verification. FDA regulations require that medical device manufacturers perform design verification to "confirm that the design output meets the design input requirements."[80] In other words, the design verification process aims to determine whether the performance specifications (design inputs) are met by the new device (design outputs).[81] The Intuitive design verification process is designed in accordance with these protocols. The goal of design verification is to objectively show that the device is built correctly from an engineering standpoint.[82]

60. Design control and risk management also involve design validation. FDA regulations also require that medical device manufacturers "establish and maintain procedures for validating . . . device design," which "ensure[s] that devices conform to defined user needs and intended uses, and . . . include[s] testing of production units under actual or simulated use conditions."[83] The Intuitive design validation process is designed in accordance with these protocols. The goal of design validation is to objectively show that the device meets user needs.[84]

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[80] Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, at 29, available at: https://www.fda.gov/media/116573/download.

[81] *Id.* at 29-30.

[82] *See* Intuitive-00477325 at Intuitive-00477381.

[83] Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, at 33, available at: https://www.fda.gov/media/116573/download.

[84] *See* Intuitive-00477325 at Intuitive-00477381-82.

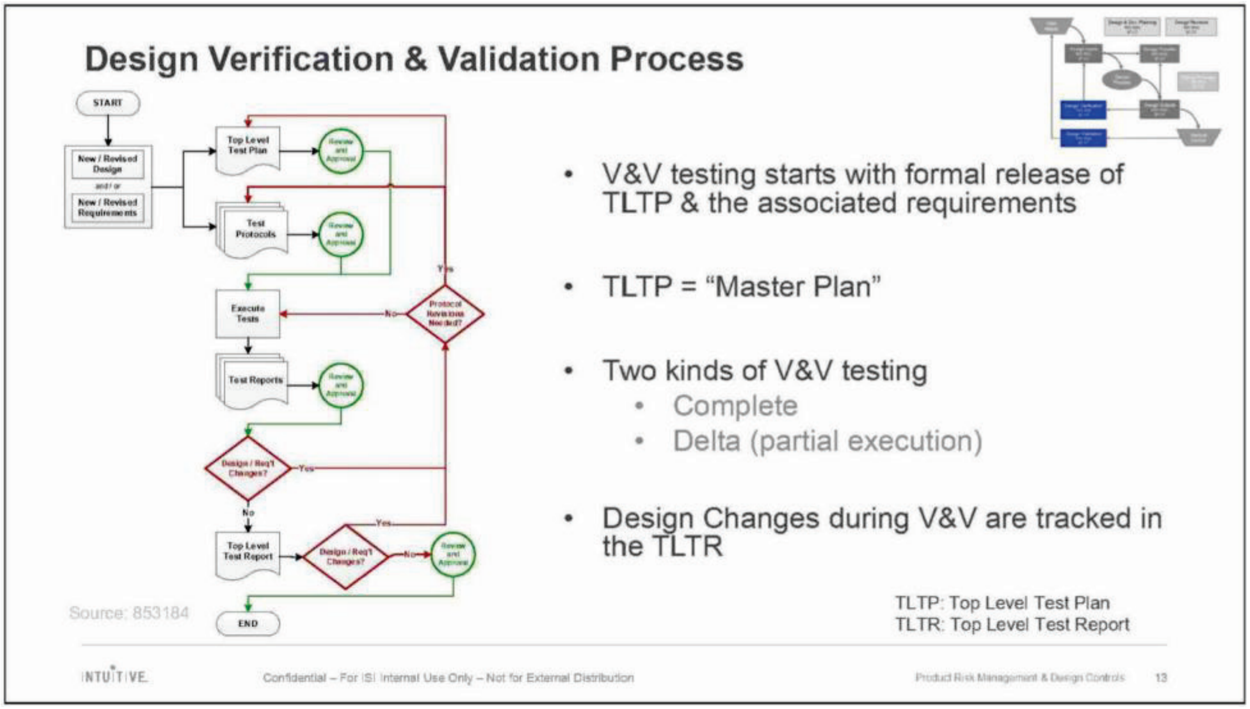

Figure 7.[85]

61. Intuitive has a formal design verification and validation process. *See* Figure 7. Verification and validation testing of a new design or a design change begins with a Top Level Test Plan ("TLTP") that describes the kinds of tests that are to be conducted and the analyses to be performed on the test data, as well as the justification for these tests that relates the specifications to the testing regimen.[86] Test protocols detail the specific steps of each test and the procedure for documenting the testing process and the results. A Top Level Test Report ("TLTR") summarizes the overall verification and validation results.[87] Test reports present the results of the testing as well as analyses and conclusions. Additional documents that specify frequently-conducted test and analysis routines such as standard operating procedures (SOPs)

[85] Intuitive-00477217 at Intuitive-00477229.

[86] Intuitive-00477217 at Intuitive-00477229.

[87] *Id.*

and department operating procedures (DOPs) are used in formulating the test documents, which may be updated as appropriate throughout the verification process.[88] Testing may range from complete tests against specifications for new device designs to more limited "delta" tests for changes to existing designs.[89]

B. Intuitive Designs and Tests Its EndoWrist Instruments to Reliably and Safely Perform Over a Set Number of "Lives"

62. Intuitive's EndoWrist instruments are designed and tested to demonstrate the instruments are safe and effective and meet all of their specified requirements and specifications, including their programmed number of instrument uses, otherwise referred to as instrument "lives."[90]

63. To verify that the design of EndoWrist instruments meets the proposed number of surgical uses, Intuitive conducts life tests.[91] This process is typically documented by a "Protocol for Reliability/Life Testing" and a "Report for Reliability/Life Testing" or similar documents.[92] These test procedures typically include initial cleaning and sterilization cycles then alternating simulated surgical procedures, sometimes also referred to as a simulated surgical use ("SSU"), and cleaning and sterilization cycles, which in combination are referred to as Surgical Use Cases ("SUCs") or life cycles. Attachments to these documents usually include sheets for recording the specific instruments undergoing testing, the equipment used, the observed

[88] *See, e.g.*, Intuitive-00544199 (referencing, among other documents, Intuitive's DOP, Product Verification and Validation (Intuitive-00477154); SOP, Statistical Techniques (Intuitive-00477757); and SOP, Risk Management (Intuitive-00477958)).

[89] Intuitive-00477217 at Intuitive-00477229.

[90] *See generally* Intuitive-00477154.

[91] *See, e.g.*, Intuitive-00544199; Intuitive-00546380; Intuitive-00547846.

[92] *See, e.g.*, Intuitive-00544199; Intuitive-00544494; Intuitive-00546380; Intuitive-00546343; Intuitive-00547846; Intuitive-00546920.

conditions during tests (e.g., sterilization temperatures), checklists for recording each step and the data that results from the tests.[93]

64. A representative example of the Intuitive life testing process is captured in the set of documents describing the life test verification of the IS1200 and IS2000/IS3000 Mega SutureCut needle driver (MSCND) and Large SutureCut needle driver (LSCND).[94] The "Protocol for Reliability/Life Test of MSCND and LSCND Improvements for Grip Cable Life" details the testing process and its justification, as well as the steps required to document the test execution and the results.[95] This protocol describes the goal of the tests in terms of functional requirements (e.g., reliable operation for ten human uses) and the instrument models to which it applies, and uses a worst-case analysis to determine which specific instrument types are most likely to experience failure and thus should be tested.[96]

65. This protocol also uses a statistical Weibull Design of Reliability analysis to determine the number of instrument samples and use cycles that are required to statistically "prove" a number of instrument lives.[97] The analysis applied in connection with the Protocol for Reliability/Life Test of MSCND and LSCND Improvements for Grip Cable Life uses a goal of 90% reliability and 90% confidence ("90/90") for ten human uses.

66. This Protocol for Reliability/Life Test of MSCND and LSCND Improvements for Grip Cable Life is a test following a design change for "updating the proximal clevis pin"

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[93] *See, e.g.*, Intuitive-00544199 (describing attachments and checklists).

[94] *See generally* Intuitive-00544186; Intuitive-00544195; Intuitive-00544197; Intuitive-00544198; Intuitive-00544199; Intuitive-00544388.

[95] *See generally* Intuitive-00544199.

[96] *Id*. at Intuitive-00544200.

[97] *Id*. Weibull Design of Reliability analysis is further detailed in the Intuitive's "Statistical Techniques – Department Operating Procedure," Intuitive-00477757.

that was instituted to "reduce the occurrence of grip cable failures."[98] The tests are designed to confirm that this change to the design maintains the specified level of reliability and confidence, so a relatively small sample size of eight units was tested due to the presence of a similar predicate device.[99] Each of these units is put through a total of 15 "life cycles," which comprise an initial six cleaning and sterilization cycles, followed by fifteen simulated surgical uses and cleaning and sterilization cycles to validate 10 human surgical uses.[100]

67. Simulated surgical procedures for life tests are described in the test report as "developed by the Clinical Development Engineering team." *See* Figure 8. The simulated surgical procedure requires a series of maneuvers of the instrument that replicate how the instrument is used in an applicable laparoscopic surgical operation. *See* Figures 8, 9, 10. In the example of the life testing of the MSCND and LSCND instruments, these steps include wrist circles (moving the instrument tip in a circular pattern), needle throws (driving the needle through a single stitch), suture pulls, tissue lifts, and tissue pushes. *See* Figure 9. Animal tissue models (in this case a beef rib roast) or synthetic models are used to provide reaction forces that emulate the forces produced in surgical procedures. *See* Figure 11. For example, the tissue push maneuver is described as "[p]ush with a force of approximately 2 lbs . . . ."[101] Maneuvers are done in an order that replicates typical surgical usage and repeated a specific number of times that conservatively approximates repetitions in surgery.[102]

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[98] Intuitive-00544199 at Intuitive-00544201.

[99] Intuitive-00544494 at Intuitive-00544494.

[100] Intuitive-00544199 at Intuitive-00544200, Intuitive-00544209.

[101] *Id.* at Intuitive-00544201.

[102] *See* Intuitive-00544494 at Intuitive-00544496.

68. By defining a simulated surgical procedure based on observed maneuvers used in applicable laparoscopic surgeries, using animal tissue or synthetic models to emulate forces used in surgical procedures, performing maneuvers in an order replicating typical surgical usage and employing a conservative approximation of the number of maneuvers to be performed during an applicable laparoscopic surgical operation, Intuitive tests instruments in a way that helps ensure the instruments operate reliably and safely over their programmed number of instrument uses.

8. Definitions

A) **Simulated Surgical Procedure** – A "Simulated Surgical Procedure" for the instrument was developed by the Clinical Development Engineering team. It is comprised of surgical tasks that are defined to represent actual maneuvers performed during minimally invasive surgical operations. The number of repetitions to be completed was determined by conservatively estimated the number of such maneuvers performed during an applicable laparoscopic surgical operation. Attachment 5 (Protocol 862287-01P) provides further details.

Figure 8.[103]

[103] Intuitive-00544494 at Intuitive-00544496.

7 Definitions

The following definitions are to describe the specific surgical maneuvers as outlined in section 12.0.

A) **Needle Throw** - Position instrument over the specified model (beef roast or uterine training model as specified in 12.7.1) in a fully wristed position – ~90° pitched or yawed. If possible, all tasks should be performed in this position. A complete throw includes driving the needle into a significant bit of tissue and pulling it completely out using the subject instrument. The assistant instrument can be used to reposition the needle between throws. Note: Uterine training model is more difficult to throw needles through and is thought to better represent the tissue encountered in most gynecological procedures.

B) **Wrist Circle** - Positioning of the instrument can be mimicked by making a looping motion with the grips in the open and closed position. Move the wrist in a circle through its entire range of pitch and yaw motion, forward and reverse.

C) **Suture Pull** - The two ends of the suture are then grasped and pulled apart to simulate tightening a knot. Wrist motion should be used to tighten the knots as much as possible.

D) **Suture Cut** – Secure a length of 0-Silk or 0-Vicryl suture so that it is lightly tensioned using two assistant instruments. Cut using the test instrument.

E) **Tissue Lift** - Grasp the beef roast with instrument. Lift the beef roast using wrist pitch or yaw.

F) **Tissue Push** - Push with a force of approximately 2 lbs using a resistive force such as rubber bands. Move the resistive load several inches. Perform with jaws closed and instrument pitched.

G) **Dips** - A dip is completed when the instrument is dipped into a fluid mixture for 3 seconds. The entire wrist should be submerged and rolled in the fluid during the dip.

H) **Instrument Changes** - Remove instrument from the PSM, then reengage the instrument on the PSM.

Figure 9.[104]

[104] Intuitive-00544199 at Intuitive-00544201.

12 Simulated Surgical Procedure (SSP)

The following table defines a clinical life simulation cycle for the MSCND instrument. This cycle utilizes the motions defined above (see section 7) and arranges/distributes them in a way that more closely approximates the expected usage patterns.

MSCND, One (1) Simulated Life Use

# of executions	Task
1	Dip
10	Needle Throws, Forehand (using Beef Roast)
10	Needle Throws, Backhand (using Beef Roast)
1	Instrument Change
Repeat Above Two Times	
1	Dip
20	Wrist Circle, Grips Closed (but not squeezed)
30	Suture Pulls
1	Instrument Change
Repeat Above Six Times	
1	Dip
10	Tissue Lift, Release
10	Tissue Push, Release.
1	Instrument Change
Repeat Above Three Times	
1	Dip
10	Needle Throws, Forehand (using Beef Roast)
10	Needle Throws, Backhand (using Beef Roast)
1	Instrument Change
Perform Above a Single Time	
30	Suture cuts
Perform Above a Single Time	

Figure 10.[105]

[105] Intuitive-00544199 at Intuitive-00544206.

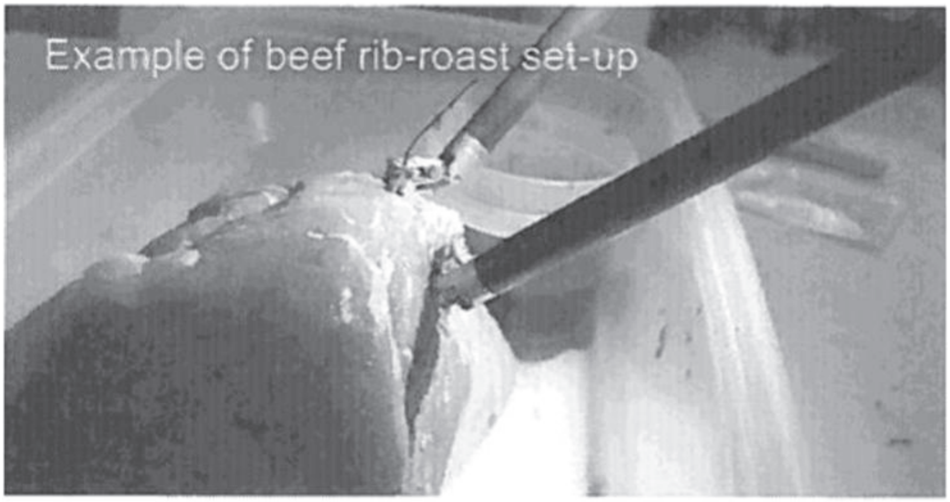

Figure 11.[106]

69. As expected with a rigorous life testing process, failures are observed during life testing of Intuitive EndoWrist instruments. In the MSCND and LSCND example, one of the eight instruments under test suffered a failure on the fourth test cycle, when "the grip close cable derailed from the distal idler pulley during testing."[107] Other examples of life testing that resulted in failures includes:

- Life testing of the 8mm permanent cautery hook, where failures were observed in three of the twelve test instruments during SUC trials 12, 17 and 21.[108]
- Life testing of 8mm monopolar curved scissors, where a derailment failure occurred in SUC trial 6.[109]

[106] Intuitive-00544456 at Intuitive-00544464.

[107] Intuitive-00544494 at Intuitive-00544500; *see also id.* at Intuitive-00544497.

[108] Intuitive-00589150 at Intuitive-00589153.

[109] Intuitive-00546920 at Intuitive-00546920. Instrument intuitive motion also failed for a different instrument in SUC trial 11 and for two additional instruments in SUC trial 12. *See id.*

- Life testing of 8mm monopolar curved scissors where a cable break was observed during SUC trial 7.[110] (Note that Intuitive considers the IS2000/3000 and IS4000 Monopolar Curved Scissors to be equivalent in terms of their distal portions.)[111]

70. As mentioned above, Intuitive has standard procedures for modeling the reliability of the instrument by fitting the life test data to a Weibull reliability model.[112] The Weibull Distribution is "a parameterized continuous probability distribution that is commonly used in failure analysis."[113] Use of the Weibull model provides the ability to predict the reliability of the instrument as a function of number of uses, as well as uncertainty estimates (confidence intervals) for these estimates.[114] This model is also used to establish testing parameters such as sample size.[115] The use of these procedures is important because it accounts for the potential for failures throughout a product's useful life and ensures instruments meet minimum reliability requirements throughout that useful life.[116] The Weibull model is a well-recognized and appropriate method for modeling the reliability of instruments.

C. As EndoWrist Instruments Are Used in a Hospital Setting to Perform Surgical Procedures, They Experience Wear and Tear that Ultimately Leads to Instrument Failure.

71. Gradual degradation of an instrument over time is expected given the design of EndoWrist instruments and it is one of the risks that is identified through Intuitive's risk analyses

[110] Intuitive-00546343 at Intuitive-00546360.

[111] *See e.g.*, Intuitive-00546343. The IS4000 system is commercially known as the da Vinci Xi surgical system.

[112] *See* Intuitive-00477597.

[113] *Id.*

[114] *See* Intuitive-00477597; Intuitive-00477620.

[115] *See* Intuitive-00477620.

[116] Intuitive-00477597 at Intuitive-00477597-98.

and life testing and is factored into EndoWrist usage limits. In addition to identified failure modes/gradual degradation inherent in normal usage, instruments are exposed to stresses by surgeons and hospital staff in the ordinary course of their use. Intuitive observes and tracks these failures in instruments that have been sold to customers and used on patients through its return material authorization (RMA) process. The RMA process allows for customers to return EndoWrist instruments that experience failure during their intended lives for a prorated discount.

72. As Intuitive notes, "RMA data is an indicator of instrument reliability because it is correlated to the number of reported instruments that do not meet performance requirements throughout their intended life. Although Intuitive performs life testing to quantify how many lives an instrument can be qualified for, there is some possibility that the assumptions made in the life testing methodology is not representative of real-world use. Although life testing is a validated process for qualifying instrument lives, Intuitive also confirms life testing data with RMA data trends, which originate from real-world use, rather than simulated surgical use, which follows methods generated within Intuitive. If RMA rates were to be misaligned with expected reliability predicted from life testing, then life testing would need to be modified to align with the reality observed through RMA rates. Neither RMA rates nor life testing is solely responsible for validating the safety of the extension of lives."[117]

73. Instruments are returned to Intuitive through the RMA process due to observed or alleged problems or failure during warranty. Intuitive has identified a variety of instrument failures—within their established usage limits—through the RMA process, including:

- Cable breakages[118];

[117] Intuitive-00004692 at Intuitive-0000470-01.

[118] *See e.g.*, Intuitive-00695006 (RMA data) at Tab 1 Row 37.

- Cable fraying[119];
- Cable derailment[120];
- Cable slack[121];
- Abuse in cleaning[122];
- Decreased electrical insulation in both cautery and non-cautery EndoWrist instruments[123]; and
- Electrode tips becoming pitted and discolored,[124] among others.

74. These failures have been observed during the warranty period, which covers only the number of lives validated by Intuitive. This RMA data provides further evidence that EndoWrist instruments can—and do—fail at times, even within the number of lives set for their use. Further, because Intuitive observes through its RMA process many instrument failures that occur as a result of wear and tear, I would expect Restore's and Rebotix's attempts to increase instrument usage limits above the limits prescribed by Intuitive will only increase failure rates. Intuitive's EndoWrist instruments have been used in millions of procedures, and Intuitive thus has a large amount of data from real-world use.[125] By contrast, there is minimal real-world use data from remanufactured instruments.

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[119] *See e.g.*, *id.* at Tab 1 Row 54.

[120] *See e.g.*, *id.* at Tab 1 Row 697.

[121] *See e.g.*, *id.* at Tab 1 Row 5284.

[122] *See e.g.*, *id.* at Tab 1 Row 121.

[123] *See e.g.*, *id.* at Tab 1 Row 856, Row 3365.

[124] *See e.g.*, *id.* at Tab 1 Row 91783.

[125] For example, Intuitive's systems were used for over 1.5 million procedures in 2021 alone. Intuitive Surgical, Inc., Annual Report 2021, https://isrg.intuitive.com/static-files/704322bf-cb0d-4ed1-954c-8eb46a070f70.

75. Via the RMA process, Intuitive also observes failures in instruments that have had their useful lives extended by third parties such as Restore and Rebotix, which were returned to Intuitive. Such failures include:

[redacted]

76. In addition, I have reviewed evidence produced by Restore of complaints it received from customers relating to failure of instruments which had usage limits extended, including:

- Failure to establish connection to or recognition by da Vinci[130];
- Missing or damaged instrument components[131]; and
- Severed cables or wires[132].

77. Based on the evidence I have observed and described above, I have noted at least 8 instances of instrument failure following the extension of an EndoWrist's useful lives by Restore.[133] In addition, I have observed evidence of at least 19 additional instrument failures

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[126] *See id.* at Tab 2 Rows 15, 17, 44 and 47.

[127] *See id.* at Tab 2 Row 24.

[128] *See id.* at Tab 2 Row 28-31.

[129] *See id.* at Tab 2 Rows 18, 28-31.

[130] Restore-00030379 at Restore-00030379.

[131] Restore-00001424 at Restore-00001424-31, 33-38.

[132] Restore-0001424 at Restore-00001424-31, 39.

[133] *See e.g.*, Restore-00001424 at Restore-00001424-31, 33-39 (7 instruments); Restore-00030379 at Restore-00030379; REBOTIX081884 at REBOTIX081884. I understand that Intuitive's damages expert in *Restore*, Dr. Loren K. Smith, identified that Restore "repaired" a total of 132 EndoWrist instruments. I am not aware of any data on the number of times each

following the extension of an EndoWrist's useful lives by Rebotix's installation of the Interceptor.[134]

VI. Limitations and Risks of the Interceptor and "EndoWrist Service Procedure"

78. The Rebotix Interceptor and the "Endo Wrist Service Procedure" developed by Rebotix are purported to extend the reliable life of certain EndoWrist instruments to at least nine surgical uses beyond their usage limit.[135] However, significant problems exist with Rebotix's approach such that in my opinion, Rebotix cannot *reliably or safely* extend the lives of EndoWrist instruments to an additional nine lives beyond their initial usage limit. In my opinion, Rebotix's service procedure and its risk management and life testing methods are flawed, making Rebotix's claim that it can reliably extend the lives of EndoWrist instruments unreliable and unsupportable.

79. Further, both Restore and SIS entirely relied on Rebotix's risk management and life testing methods, rather than performing their own assessments of the reliability of extending the useful lives of EndoWrist instruments.[136] Since Rebotix's safety and reliability claims were

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"repaired" instrument was actually subsequently used during a procedure. Notably, the failures described and identified above only incorporates evidence of failures produced by Restore in this litigation or identified through Intuitive's RMA process. While I do not have complete information on the number of failures that occurred among EndoWrist instruments that had usage lives extended by Restore, I would expect the actual number of failures to be higher.

[134] *See e.g.*, REBOTIX045741 at REBOTIX045741; REBOTIX000874 at REBOTIX000875; REBOTIX088383 at REBOTIX088386 (3 instruments); REBOTIX060630 at REBOTIX060630-31; REBOTIX082118 at REBOTIX082118-9 (2 instruments); REBOTIX084983 at REBOTIX084983-84; REBOTIX000664 at REBOTIX000664; Intuitive-00695006 at Tab 2 Rows 15, 17, 20, 24, 44, 47 (6 instruments); CRMC 295 at CRMC 306 (3 instruments).

[135] REBOTIX162404 at REBOTIX162404.

[136] May 6, 2021 Kevin May Tr. at 54:17–55:8, 129:3–130:21, 164:15–165:20; June 8, 2021 Kevin May Tr. at 245:13–16; Nov. 1, 2022 Greg Posdal 30(b)(6) Tr. at 22:24–23:2, 23:23–24:1, 25:1–6, 29:6–11, 30:8–13, 32:4–6, 49:23–50:3.

unreliable and unsupportable, both Restore's and SIS's safety and reliability claims are therefore similarly unreliable and unsupportable.

A. Risks Associated with the Rebotix "EndoWrist Service Procedure"

80. Rebotix describes the installation of the Rebotix Interceptor in a document titled the "Endo Wrist Service Procedure."[137] In addition, I understand that Rebotix created a video for the purpose of demonstrating the Rebotix service procedure to customers, which I reviewed in connection with the "EndoWrist Service Procedure".[138] Both the service procedure documentation and video demonstrate a number of deficiencies in the Rebotix Interceptor installation process that pose risks to both instrument functionality as well as patient safety.

81. The "EndoWrist Service Procedure" begins with a recitation of precautions, warnings, and safety information, and a list of required equipment, parts and supplies.[139] The initial steps of the "EndoWrist Service Procedure" include connecting the instrument to an electronic test fixture to access information about the instrument[140] and visual inspection of the instrument,[141] followed by dielectric and electrical resistance testing of cautery instruments.[142]

[137] *See* REBOTIX162404.

[138] Deposition testimony indicates that Rebotix's EndoWrist "repair" processes was captured in REBOTIX175327, which was then shown to customers and potential customers, in order to demonstrate Rebotix's services. June 22, 2021 Gibson Dep Tr. at 136:1-137:5, 171:20-172:12, 186:4-10.

[139] REBOTIX162404 at REBOTIX162405-08.

[140] The information accessed is: (1) the number of current available uses; (2) the EndoWrist's Serial Number; (3) the EndoWrist Device Type; and (4) the DS2505 Serial Number. REBOTIX162404 at REBOTIX162411-13.

[141] REBOTIX162404 at REBOTIX162404-13.

[142] REBOTIX162404 at REBOTIX162413-17.

The proximal housing is then opened and visually inspected, and the injection port and tube are removed.[143]

82. Next, in cases where the instrument has not previously had the Rebotix Interceptor installed, the original circuit board is removed. Removal of the original printed circuit board (the "PCB") requires milling away an unspecified amount of material from the existing printed circuit board mounting and prying it from its mounting pins. The DS2505 chip that contains instrument usage data is desoldered from the original PCB and then resoldered on a new Interceptor PCB. A conformal coating is then manually applied to the new PCB and cured.[144]

83. Next, Rebotix performs tool "repairs." The instrument's cables are manually tensioned and the jaws are aligned and sharpened using pliers and files, as relevant for the instrument type. Metal surfaces are then polished and the instrument is cleaned. Next, the Interceptor PCB is mounted in the instrument.[145] The original mounting clips are hammered flat and then replaced on the mounting pins. The injection port and tube are reinstalled, and the housing cover is replaced.[146]

84. The same tests that were run at the beginning of the service procedure are then repeated: Rebotix's electronic test fixture is used to confirm that the number of available uses value is now "10" (and that all of the other information (e.g., EndoWrist serial number) remains unchanged), the same visual inspection that was performed pre-servicing is repeated, and the

[143] REBOTIX162404 at REBOTIX162418.

[144] REBOTIX162404 at REBOTIX162418-21.

[145] REBOTIX162404 at REBOTIX162422.

[146] REBOTIX162404 at REBOTIX162422-23.

dielectric and electrical resistance testing of cautery instruments that were performed initially (pre-"repair") are repeated as well.[147]

85. There are a number of potential risks associated with Rebotix's servicing of EndoWrist instruments as described in the "EndoWrist Service Procedure," demonstrated in the video, and summarized above.

86. First, multiple steps in the procedure generate particulate debris, including:

(1) "6.1.7 Use a Dremel with a small etching bit to remove a small amount of material from the PCB alignment pins"[148];

(2) "6.1.11 Using the Dremel, drill bit, and drill stop (set to approx. 23mm) to drill the pilot hole for the Screw to be added later"[149];

(3) "6.4.2.2. Files can be used to correct any misaligned or damaged grasper teeth"[150];

(4) "6.4.2.3. For scissors . . . . [i]f sharpening is needed, use the #6 and # 10 cut files to hone the cutting edges as needed"[151]; and

(5) "6.4.3.2. Under magnification, use the Dremel and the abrasive buff to lightly polish all metal surfaces to achieve a uniform satin finish."[152]

87. Notably, while each of these steps within Rebotix's process generates particulate debris, methods for thoroughly removing this debris are not provided in the "EndoWrist Service Procedure," and inadequate methods are prescribed. For example, after the drilling of a hole in

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[147] REBOTIX162404 at REBOTIX162424.
[148] REBOTIX162404 at REBOTIX162418.
[149] REBOTIX162404 at REBOTIX162419.
[150] REBOTIX162404 at REBOTIX162422.
[151] REBOTIX162404 at REBOTIX162422.
[152] REBOTIX162404 at REBOTIX162422.

the instrument, Rebotix recommends that the technician "brush off any debris created from the drilling process."[153] Based on my experience, brushing is not effective for removal of debris from the complex internal geometry of the exposed instrument mechanism (including recesses and cavities) after the cover has been removed. In the service procedure video, Rebotix's technician attempts to remove debris by blowing on the instrument with his mouth and brushing the instrument with his fingers, neither of which is an adequate means to effectively remove debris.[154] While earlier Rebotix documents refer to ultrasonic cleaning procedures for removing debris,[155] those procedures are not referenced or incorporated into Rebotix's 2019 EndoWrist Service Procedure documentation.[156] Additionally, while the Rebotix EndoWrist Service Procedure mentions ultrasonic cleaning as one option for removing debris, it also offers the option to "clean with alcohol/acetone,"[157] which in my experience would be inadequate to effectively remove debris.

88. Similarly, the process for removing the original PCB mounting clips requires removing an unspecified "small amount of material" from the PCB mounting pins.[158] When the pins are subsequently flattened by hammering and replaced on the pins to retain the Interceptor PCB, they will not have adequate holding force if too much material has been removed. This

[153] REBOTIX162404 at REBOTIX162420.

[154] REBOTIX175327.

[155] *See, e.g.*, REBOTIX133239 at REBOTIX133240 (dated Sept. 17, 2014); REBOTIX133272 at REBOTIX133273–74 (dated Sept. 17, 2014); REBOTX133279 at REBOTX133280 (dated Sept. 17, 2014).

[156] *See generally*, REBOTIX162404.

[157] *Id.* at REBOTIX162422

[158] *Id.* at REBOTIX162418.

could result in loose parts that interfere with operation of the cable drive components in the proximal housing, as well as generating debris that could fall into the surgical field or the patient.

89. Intuitive engineering documents describe this type of particulate contamination as a serious potential risk. For example, the 8mm instrument FMEA indicates that potential failures for various components within the proximal housing could result in "[p]arts or fragments fall[ing] into patient"; Intuitive assigns this risk a severity score of 9 out of 10 and requires mitigation by life testing.[159]

90. I understand that one of Plaintiff's experts has opined that he has "never encountered a situation in which a malfunctioning EndoWrist harmed a patient or member of the surgical team, or negatively impacted a successful patient outcome," and that instrument failures can be addressed by the surgeon during a procedure.[160] The contamination risks just described—e.g., debris falling into a patient—could occur without the surgeon noticing them and without the device itself becoming unusable. The presence of manmade materials within the body can trigger the well-known foreign body reaction, which is an inflammatory process that can lead to pain, adhesions, infections, and disruptions of normal physiological function.[161] Even microscopic debris (e.g., filaments from a broken cable) can lead to serious adverse responses in patients following surgery.[162]

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[159] *See* Intuitive-00538994 at Tabs 1, 2, and 11.

[160] *See, e.g.*, Mahal Rep. ¶¶ 57, 61.

[161] Anderson, James M., Analiz Rodriguez, and David T. Chang. "Foreign body reaction to biomaterials," in *Seminars in Immunology*, vol. 20, no. 2, pp. 86-100, 2008; Wang, Cecily F., James Cipolla, Mark J. Seamon, David E. Lindsey, and S. Peter Stawicki. "Gastrointestinal complications related to retained surgical foreign bodies (RSFB): A concise review," in OPUS 12: 11-8, 2007.

[162] Truscott, Wava. "Impact of Microscopic Foreign Debris on Post-Surgical Complications," in *Surgical Technol. Int'l*, vol. 12:34-46, 2004.

91. Furthermore, Rebotix was aware that this is a serious issue. Rebotix analyzed a "Risk Management Report Remanufactured EndoWrists" document, which reported EndoWrist failures in the FDA's Manufacturer and User Facility Device Experience Database (MAUDE), as detailed in paragraph 107 below. This document recounted that the database analysis revealed 173 adverse events attributed to the da Vinci system, and approximately half involving debris falling into the patient, some of which were reported as injury to the patient (Figure 12).

- There were a total of 173 distinct MDR's from all causes that could be attributed to the Da Vinci system. Based on careful review of each report, 13 of these events clearly led to patient injury that was potentially serious.
- Approximately half of the events involved debris falling into the surgical site. In all but 13 of these events, all debris was retrieved. In cases where some debris may have been left behind, the event was often still not reported as an injury to the patient.

Figure 12.[163]

92. Another issue arises from the instructions in Rebotix's service procedure regarding the tensioning of cables within instruments. While Intuitive uses specific tools (e.g., a tensioning tool and 40 in-oz torque driver as well as test fixtures for the instrument) to pre-tension cables to specific values to counteract the anticipated cable-stretch over the life of the instrument,[164] Rebotix uses a much less precise method. Rebotix instructs technicians to manually adjust the tension on the drive cables by "[u]sing the screwdriver turn the spool to apply tension to the cable," noting that, "[o]nly enough tension to remove the slack from the cable is required."[165] Rebotix also warns against "over tension[ing] the cable as this could create

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[163] REBOTIX133038 at REBOTIX133040.

[164] *See supra* ¶ 45 (*citing* Intuitive-00537574 at Intuitive-00537575 and Intuitive-00705141 (Intuitive Manufacturing Process Instructions (MPI) Cable Tensioning, 838012); *see also* Nov. 8, 2022 Grant Duque (30(b)(1)) Tr. at 136:20–146:13.

[165] REBOTIX162404 at REBOTIX162422. This procedure is described in the "EndoWrist Service Procedure" document, which is dated January 25, 2019. Another document produced by Rebotix, dated five years earlier, identifies a different procedure for adjusting cable tension ("2014 Procedure"). *See generally* REBOTIX133344. It is unclear which procedure Rebotix actually uses to attempt to adjust cable tension, but both processes are flawed. In the 2014

problems during use."[166] The Rebotix Process, however, does not provide specifications or instructions for determining whether the cable is over-tensioned or under-tensioned. Nor did Rebotix have access to Intuitive's original equipment specifications to know the appropriate level of tensioning.[167]

93. This difference between Intuitive and Rebotix protocols has potential consequences to instrument reliability and patient safety. Improper tensioning of the instruments' cables can lead to instrument failure, as observed in Intuitive life testing: under-tensioning can lead to derailments, while over-tensioning can contribute to cable wear and premature cable and bearing failure and increase friction in the drive system, which can reduce the range of motion and limit grip forces.[168] There is no indication in the EndoWrist Service Procedure that Rebotix understands the need to tension to a specific value to ensure that the instrument retains function over extended uses.[169]

94. The prescribed visual inspection procedure (Step 5.2 of the "EndoWrist Service Procedure" and repeated in Step 7.2) is also inadequate to detect serious problems with an instrument. In general, the procedure provides only general instructions but does not explain what specifically should be checked. For example, in step 5.2.4 the procedure instructs the

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Procedure, for example, the adjustment to the cable spool is apparently made by hand, while the operator's other hand holds "modified dental pick" to re-spool the cable. *Id*. at REBOTIX133346.

[166] REBOTIX162404 at REBOTIX162422.

[167] June 22, 2021 Chris Gibson Tr. at 58:13–59:4.

[168] *See, e.g.*, Intuitive-00538913 at "2) IMA Backend Assy Processes" Rows 40, 41; Intuitive-00544494 at Intuitive-00544497. Rebotix also acknowledges problems can result from over tensioning, though it fails to acknowledge risks associated with under-tensioning. *See* REBOTIX162404 at REBOTIX162422.

[169] *See, e.g.*, Intuitive-00537574 at Intuitive-00537575 ("When each instrument is manufactured, the axis cables are tensioned to specific values. The tension ensures that the instrument remains functional throughout its lifetime as cable stretch occurs.").

technician to "[v]erify that the manipulation wheels move freely in each direction throughout its full intended range of motion" but provides no guidance on what the full intended range of motion should be.[170] Moreover, only limited and inadequate inspection is required for components within the proximal housing, although the proximal housing contains numerous essential elements of the cable drive system that are exposed during servicing.[171] RMA results show failure modes that should be checked, including frayed cables within the proximal housing[172] and corrosion or contamination of the instrument bearings.[173] Finally, as noted above in section IV.B, even a thorough visual inspection is inadequate to detect serious deficiencies in the cable drive system.[174]

95. In addition to the issues detailed above, there are numerous other problematic aspects of Rebotix's servicing procedure. First, although electrostatic discharge is a well-known cause of failures in electronics manufacturing, the technician shown on Rebotix's service video does not use electrostatic discharge (ESD) precautions when handling the Interceptor PCB.[175] Second, the Rebotix technician shown on the video uses compressed air from a hose to remove liquid from the instrument after ultrasonic cleaning.[176] This appears to be "shop air" that is traditionally provided in labs and fabrication shops. Typically it is not filtered and often contains

[170] REBOTIX162404 at REBOTIX162413.

[171] REBOTIX162404 at REBOTIX162413.

[172] *See, e.g.*, Intuitive-695006 (RMA data) Tab 1 at Row 16798, 40346.

[173] *See, e.g.*, Intuitive-695006 (RMA data) Tab 1 at Row 173, 579.

[174] U.S. Navy Wire-Rope Handbook, Vol. 1, p. 3-15 (explaining that "[c]orrosion within a wire rope is almost impossible to detect visually, which makes it extremely difficult to determine the true condition of a corroded rope.").

[175] REBOTIX175327. Although the SOP does address and attempt to account for ESD, the technician on the service procedure video does not appear to take any such precautions.

[176] REBOTIX175327.

contaminants from the compressor and piping, and thus can introduce additional contamination to the instrument, both on the surface and in internal spaces that are problematic to clean. The Rebotix servicing procedure calls for use of "compressed air" to dry the instrument but gives no guidance or specification for its quality.[177]

B. Rebotix's Inadequate Risk Management and Life Testing

1. Rebotix's Risk Management

96. Rebotix devised and executed a risk management process for its "remanufactured" instruments, including FMEA analysis and life testing. There are, however, a number of deficiencies in these procedures. In particular, the risk management process assumed that the Rebotix servicing procedure could restore instruments to a like-new state, ignoring the impact of the stresses that typical surgical use imparts to instruments and, as explained at length above, leads to failures. In addition, it appears that Rebotix's risk management process gives little or no consideration to mechanical failures, although the importance of mechanical failures is clear from Intuitive's risk management activities for EndoWrist instruments, as well as Rebotix' own risk management documents.[178]

97. In support of my analysis of Rebotix's risk management practices, I reviewed the documentation identified by Rebotix as the "Rebotix Endowrist Risk management File" as

[177] REBOTIX162404 at REBOTIX162422. By contrast, Intuitive's reprocessing instructions refer specifically to "clean, dry air" when air is used to dry EndoWrist instruments after sterilization. *See, e.g.*, da Vinci S and Si Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, at 36, https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=d237e175-3fce-3844-863e-37e733afe0d6&groupId=73750789; da Vinci Xi Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, at 36, https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=b1b9f169-4503-9ea9-6db9-9243c28d5221&groupId=73750789. "Clean air" is a widely used term that refers to a specific quality of air that is higher than "shop air."

[178] *See e.g.*, Intuitive-00538994 (8mm Instrument Family FMEA with various tabs devoted to potential mechanical failures).

part of the technical file review located at REBOTIX162889. The technical file review identifies the following six component parts of the "Rebotix Endowrist Risk management File": (1) Risk Management Plan; (2) Design Failure Mode and Effects Analysis; (3) Risk Management Report; (4) IEC 60601 Risk Management Table; (5) Rebotix Endowrist MDR Report; and (6) Rebotix Endowrist MDR Sub Report.[179]

98. The central assumption of Rebotix's risk management for EndoWrist instruments is that their remanufacturing process restores instruments to like-new "OEM product" conditions. Thus, risks due to wear and tear from continued use beyond the originally programmed lives are not considered to be significant. This is described in the Rebotix "Risk Management Plan."[180]

> Due to considerations that are unique to the situation of remanufacturing the EndoWrists, the following conventions will be adopted for the design FMEA:
>
> - The baseline risks inherent in the OEM product will be estimated as "pre-mitigation" risks, and OEM risk controls will be identified.
> - Actions, mitigations, or control measures will be implemented to ensure that risk levels for remanufactured EndoWrists do not exceed those that were estimated for the OEM device. Remanufacturing does not affect the design of the EndoWrists (except for modifications to the use count chip), so many of the risk controls will be process-based methods of restoring OEM design mitigations.
> - In addition to the risk acceptability levels established below in Table C, any estimated hazard severity or probability of occurrence for the remanufactured EndoWrists that exceeds that estimated for the OEM Endowrists will be considered unacceptable.

99. This concept is reiterated throughout Rebotix's "Risk Management Report." For example:

> It is presumed that all risks related to the OEM EndoWrists, as they are originally placed on the market, have been controlled to an acceptable level. As such, the risk management approach adopted was to analyze the known and potential hazards inherent in the OEM Endowrists, and then use appropriate risk controls to ensure

[179] *See* REBOTIX162889 at REBOTIX162901.

[180] REBOTIX123792 at REBOTIX123794.

> that the probability of any resulting harms occurring is no higher in remanufactured Endowrists than it is in OEM Endowrists. Many of the controls employed by Rebotix will actually serve to restore design-based mitigations of the OEM devices, and will ultimately be process-based, by nature.[181]

100. Rebotix ignored, however, the key Intuitive risk control measure of limiting the number of surgical uses and assumed that wear and tear that occurred after new instruments satisfied "OEM-equivalent specification" was negligible.

101. Also as part of its risk management analyses, Rebotix performed a design FMEA and identified a number of potential risks involving mechanical failures.[182] One example is the entry on line 26; under "Key process step or input" / "Potential Failure Mode" / "Potential failure Effect," Rebotix lists "Cable torque shall allow for the 4 degrees of freedom (wrist pitch, wrist yaw, roll, and grip) / User unable to manipulate tool end as needed during a procedure (slack in cable) / Device performs poorly during procedure, Possible serious injury (surgical intervention required)."[183] Regarding this risk, for "Actions, mitigations, or control measures implemented"/ "Verification of risk control" Rebotix lists "Cable torque procedures and inspection PR3043, PR3050, PR3052" / "Simulated life testing (ALL - see note 1)." The referenced documents provide instructions on inspecting used instruments and setting the cable tensions.[184] None of the

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[181] REBOTIX133038 at REBOTIX133039. *See also, e.g.*, REBOTIX133038 at REBOTIX133041 ("Consistent with the approach of restoring the remanufactured Endo Wrists to OEM-equivalent specification, the most common risk control utilized was to restore risk controls that were inherent in the OEM design.").

[182] REBOTIX084174.

[183] REBOTIX084174 at REBOTIX084176.

[184] REBOTIX121303; REBOTIX123447; REBOTIX133344. Although these documents describe a quantitative cable tensioning procedure, the EndoWrist servicing procedure, REBOTIX162404, spells out a different, qualitative procedure: "Only enough tension to remove the slack from the cable is required. Do not over tension the cable as this could create problems during use." REBOTIX162404 at REBOTIX162422.

listed "Actions, mitigations, or control measures implemented," however, is adequate to restore an instrument that has been used in repeated surgical procedures to a state that is equivalent to OEM specifications for a new instrument. As noted above, during normal use of an EndoWrist instrument, drive cables may be damaged, bearings may be contaminated, and other faults may arise that are not visible under inspection. *See supra* § V.C.

102. Rebotix's treatment of many other risks in its FMEA suffers from a similar reliance on inadequate procedures and testing.[185] In addition, and as shown below, Rebotix life testing does not adequately simulate the forces and interactions in surgery, so these measures are inadequate to ensure reliability of remanufactured instruments.[186]

103. I also reviewed Rebotix's "Interceptor Circuit Card Risk Analysis and Assessment," which limits its analysis to the Interceptor circuit card itself and the procedure whereby the card is inserted and does not consider mechanical interactions of the instrument during surgery.[187] Rebotix repeatedly and explicitly indicates that the analysis within refers only to the risks related to the installation and function of the interceptor chip. In section 1.2, the "Document overview," Rebotix notes that "[t]his document assesses any potential additional patient or user risk that might be introduced by the Interceptor Circuit Card Assembly installed in EndoWrist® Instruments used by the da Vinci® Surgical System."[188] Furthermore, in section 2.4, "Characteristics Affecting Safety," Rebotix states:

> Sub-clause 4.2 of ISO 14 971 requires the identification of those characteristics of medical devices that could affect safety. The following table of questions and answers are considered in the

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[185] *See, e.g.*, REBOTIX084174 at REBOTIX084175-76 (Rows 17-34).

[186] *See e.g.,* REBOTIX170053 at REBOTIX170128, REBOTIX170180, REBOTIX170235, REBOTIX170283 (discussed below at ¶ 97).

[187] REBOTIX084679.

[188] REBOTIX084679 at REBOTIX084683.

> context of use of the Interceptor Circuit Card Assembly. The first part of each answer addresses the question in context of the surgical system, and the second part of each answer is in the context of the Interceptor's role.[189]

104. Then line C.2.22 of the ensuing table states[190]

C.2.22	To what mechanical forces will the medical device be subjected?	Since the da Vinci® Surgical System acts as a computer assisted extension of the surgeon's instruments, the EndoWrist® will experience the same physical forces as those experienced by surgical implements. Endoscopic Instruments may include rigid endoscopes, blunt and sharp dissectors, scissors, scalpels, shears, forceps/pick-ups, needle holders, retractors, stabilizers, and accessories for manipulation of tissue. Due to its design and location within the EndoWrist® housing, the Interceptor Assembly will not be subjected, nor be impacted by, any of these mechanical forces.

105. Similarly, section 2.6, "Risk Analysis and Evaluation," includes an FMEA analysis table which (referencing the life testing discussed below) considers potential failures of the Interceptor itself, but lacks any consideration of failures due to the mechanical interactions that will occur during surgical use of the serviced devices.[191] Thus, the report fails to consider the role of mechanical forces to which the serviced instruments will be subjected during their extended life.

106. The overall strategy of ignoring wear and tear and assuming that the remanufacturing process restores device specifications to an OEM-equivalent state is also explicitly stated in Rebotix's "IEC 60601 Risk Management Matrix."[192] This document

[189] REBOTIX084679 at REBOTIX084685.

[190] REBOTIX084679 at REBOTIX084688.

[191] REBOTIX084679 at REBOTIX084693.

[192] REBOTIX084240 at REBOTIX084242-45.

enumerates the Rebotix risk assessment for the remanufactured EndoWrists under the requirements of ISO standard IEC 60601, which is the "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance."[193] The matrix provides entries for the 14 "clauses" (categories of requirements) of ISO standard IEC 60601.[194] Under "Justification for Exclusion or Description," Rebotix states that it need not consider design-related risks: "The device design specifications and design-related risk management file resides with the OEM. The remanufacturing process restores device specifications to an OEM-equivalent state, and does not alter them." This entry appears under 13 of the 14 clauses.[195] Again, this ignores the effects of continued usage.

107. Finally, it is clear that Rebotix was in possession of data and analyses that showed that mechanical failures represented a large portion of all failures observed in EndoWrist instruments, and that showed the increased risk of continued use of EndoWrist instruments beyond their originally specified number of uses. The "Risk Management Report"[196] references reports Rebotix commissioned that analyze EndoWrist problems and failures through the FDA's Manufacturer and User Facility Device Experience Database (MAUDE):

> Since Rebotix did not have access to the OEM compliant files, an assessment of publicly-available complaint information was required in order to estimate the current probability of occurrence rates for OEM Endowrist failure modes. An exhaustive review and analysis of the FDA MAUDE database and other available sources of relevant information was performed and documented in the report, 420000-001 Rev 2 "Rebotix Endowrist MDR Report".[197]

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[193] REBOTIX162889 at REBOTIX162903.

[194] REBOTIX084240 at REBOTIX084242-45.

[195] *Id.*

[196] REBOTIX133038.

[197] REBOTIX133038 at REBOTIX133039. The FDA website provides a description of MAUDE: "Manufacturer and User Facility Device Experience (MAUDE) database represents

108. The referenced report—the "Rebotix Endowrist MDR Report"[198] and the accompanying "Endowrist MAUDE Sub Report"[199]—contain a detailed analysis of instrument issues reported to the FDA for 2007 to 2012. These analyses show that mechanical failures were among the most common issues, and that issues increased with the number of uses.

109. Numerous mechanical failures are reported throughout these documents. For example, page 8 of the Rebotix Endowrist MDR Report notes[200]:

Broken and Foreign Bodies
The grouping of "Broken" consists of any mention of broken grips, broken wires, broken clevis, conductor caps, blades tips, etc., in either the Event Description or the Manufacturer's Narrative. Almost half of all the MDR's indicate something broken.

110. Similarly, a count of keywords in the descriptions of instrument failures for the ProGrasp Forceps showed that 17 of 52 observed issues involved the cable drives, e.g., "grip cable derailed at distal idler" and "pitch cable broken at distal clevis."[201] The same pattern of a large fraction of the failure reports mentioning cable issues is observed for many of the instruments analyzed.

reports of adverse events involving medical devices. The searchable database contains the last 10 years of medical device report (MDR) data. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 CFR 803.19. The downloadable data files consist of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. The public may search the database for information on medical devices that may have malfunctioned or caused a death or serious injury. Data for the past 10 years is available through the end of the previous month." U.S. Food and Drug Admin., Manufacturer and user facility device experience database – (Maude), https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/manufacturer-and-user-facility-device-experience-database-maude (last visited Jan. 18, 2023).

[198] REBOTIX090153. MDR refers to FDA Medical Device Reporting, *see* https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

[199] REBOTIX089889.

[200] REBOTIX090153 at REBOTIX090160.

[201] REBOTIX090153 at REBOTIX090168.

111. Evidence that increased instrument problems correlated with increased instrument usage was identified in the MDR report.[202] This analysis "..shows the returned Endowrists and how many lives were left."[203] For instruments that started with 10 lives, the data shows that most of the failures (53%) occurred in instruments with 3 or fewer lives remaining, while only 19% of failures occurred in instruments with 7 or more lives remaining.[204] This data demonstrates to a statistically significant degree that instruments wear out and show increased failure rates with increased usage.

112. In summary, the Rebotix risk management approach is flawed. It assumes that EndoWrist instruments could be serviced to restore the same level of reliability as new instruments, and ignored the damage that occurs in normal surgical use of these instruments. This is evident throughout the pertinent Rebotix documentation, from the high-level Risk Management Plan and Report, to specific documents such as the FMEAs for the instruments and the Interceptor and the 60601 Risk Matrix. In addition, the risk management process failed to recognize the frequency of mechanical failures, even though reports they commissioned clearly showed the prevalence of such failures. This error was compounded in the Rebotix life testing described below, where the mechanical loading used was inadequate to simulate actual surgical conditions and thus failed to produce a realistic mechanical failure rate.

2. Rebotix's Life Testing

113. Rebotix also purported to perform life testing on EndoWrist instruments in order to "demonstrate that [EndoWrist instruments] would consistently meet specified safety and

[202] REBOTIX090153 at REBOTIX090164.

[203] *Id.*

[204] *Id.*

performance requirements through the rigors of eleven simulated use cycles following re-manufacture."[205] However, as with Rebotix's risk management procedures, there are numerous deficiencies in Rebotix's life testing.

114. Rebotix's selection of specific models for life testing was based on a purported worst case analysis.[206] Rebotix notes that, "[f]or the purpose of life testing, worst case means that no other Wrists represent a greater risk of failure."[207]

115. Rebotix established worst case instruments by determining that: "1. Each Tool End Design (Scissors, Graspers, Needle Drivers, and Non-Operating Cautery) must be challenged. 2. Each Energized Wrist Type (Monopolar, Bipolar, and PK) as well as non-energized Wrist type must be challenged. 3. Each Part per the Part Index must be challenged."[208]

116. These criteria do not include the role of forces in limiting instrument life. In contrast, Intuitive's life test verification of EndoWrist instruments involves subjecting instruments to forces—similar to those encountered during surgery—that can and do limit instrument life.[209] For example, as discussed in Section V.B above, Intuitive's delta life test verification of the IS1200 and IS2000/IS3000 Mega SutureCut needle driver (MSCND) and Large SutureCut needle driver (LSCND) used animal tissue models to provide reaction forces (e.g., forces of approximately 2 lbs) simulating those forces produced in surgical procedures.[210] In the case of the MSCND and LSCND instruments, one of the eight instruments tested failed on

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[205] REBOTIX170053 at REBOTIX170053.

[206] REBOTIX146770 at REBOTIX146771.

[207] REBOTIX146770 at REBOTIX146771.

[208] REBOTIX146770 at REBOTIX146772.

[209] *See generally* Intuitive-00544199; Intuitive-00544494.

[210] Intuitive-00544199 at Intuitive-00544201.

the fourth test cycle due to a cable derailment.[211] Moreover, Intuitive's worst-case analysis for its instruments includes and accounts for mechanical forces, for example, Intuitive selects the instruments that have the highest design loads (defined as the "comparative ranking of the stress an instruments drivetrain components are subject to during use") or the highest levels of cable tension as worst-cast instruments.[212]

117. Rebotix's life testing did include some interactions with chicken breast that were intended to simulate what the instruments would experience during actual surgical procedures. For example, to simulate the use of cautery instruments during surgery, the instruments applied a series of burns to chicken breast,[213] and to simulate the grasping of tissue, the instruments grasped chicken breast.[214] However, in none of the tests was significant force applied to the instruments, as would happen during an actual surgical procedure. This is in contrast to Intuitive life testing, where large forces are required to be applied to the instruments to simulate both tissue interactions and collisions or other interactions between instruments.[215] The greater forces applied to instruments by Intuitive during life testing, which more realistically simulate actual clinical use, increase the amount of wear and tear an instrument experiences during life testing.

118. Rebotix's inadequate life testing also does not appear to include any statistical analysis, like Intuitive's Weibull Design of Reliability analysis, to determine the number of instrument samples and use cycles that are required to statistically "prove" a number of instrument lives. This flaw is significant because, as discussed above, Weibull Distribution

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[211] Intuitive-00544494 at Intuitive-00544497.

[212] Intuitive-00027876 at Intuitive-00027879-00027881.

[213] REBOTIX170053 at REBOTIX170235.

[214] REBOTIX170053 at REBOTIX170128; REBOTIX170180; and REBOTIX170283.

[215] Intuitive-00544199 at Intuitive-00544201 (noting that "2 lbs" of force applied in the MSCND and LSCND tests).

accounts for the potential for failures throughout a product's useful life and supports reliable performance throughout that useful life.[216] Instead, it appears Rebotix assumes that all S/Si instruments are reliable to a certain number of uses as long as the test instruments did not fail throughout that number of life cycles.[217] Even if Rebotix's life testing were adequate to simulate surgical uses (and it is not, for the reasons described above), Rebotix's approach to life testing fails to account for potential failures throughout an instrument's useful lives that might not be caught in life testing and also fails to build in any safety margin beyond the number of uses tested.

119. Rebotix claims it builds in a 20% safety margin to its life testing by adding 12 "exercises" beyond the 60 it deems necessary for a simulated use cycle for a total of 72 exercises.[218] "Exercises" are defined as the manipulations/activations that an instrument performs during surgery (e.g., moving through a range of motion, cutting and grasping).[219] However, this approach to building in a safety margin is flawed for at least two reasons: First, as described above, Rebotix life testing does not adequately replicate the forces exerted during surgical uses. Second, by opting for a longer surgical use cycle, rather than testing instruments for additional uses, Rebotix life testing excludes additional reprocessing cycles. Intuitive, by contrast, builds in a safety margin based on additional uses, which requires it to subject its life testing instruments to additional surgical use cycles *and* additional reprocessing cycles to build in a safety margin. Intuitive's approach better approximates actual surgical use, which necessitates a reprocessing cycle to ensure the instrument is sterile before it is used on a patient.

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[216] *See supra* ¶ 70 (citing Intuitive-00477597; Intuitive-00477620).

[217] REBOTIX170053.

[218] S*ee* REBOTIX170053 at REBOTIX170053.

[219] *See id.*

120. The deficiencies with Rebotix life testing are made even clearer when compared with the results Intuitive experienced during its life testing in conjunction with its Extended Use Program for certain X and Xi instruments. The Extended Use Program aimed to take advantage of diverse improvements in instrument design and reprocessing practices relevant to the X and Xi instruments to enable customers to use certain X and Xi instruments for more than the originally validated ten lives. The "White Paper, Extended Lives Supporting Materials" document provides details on the program and the life testing that provided the basis for life extension:

> Da Vinci instruments, which are used in procedures and are reprocessed between uses, experience degradation throughout their lifetime. Instrument degradation can eventually lead to poor instrument performance or a device failure. To ensure reliability and reduce the possibility of instrument failures occurring during a procedure, the number of uses per instrument are limited. Fewer instrument lives increases confidence of adequate performance, but also results in additional customer cost by requiring more frequent replacement and purchasing. Based on a number of design and manufacturing improvements made over the past several years, as well as efforts to reduce reprocessing practices at hospitals, and in an effort to reduce costs for the customer, a number of X/Xi instruments have been re-evaluated for extended life reliability. The results of this testing have made it possible to increase certain instruments' rated use and reprocessing life, while still ensuring safe and adequate performance throughout the instrument lifetime, with no impacts to our risk-based confidence and reliability requirements....
>
> To analyze the ability of instrument lives to be extended safely, life testing was performed on X/Xi instruments and a cumulative risk analysis was completed and summarized. Life testing that was used previously to validate the specification of 10 lives (for most instruments) was completed "to failure" to determine the maximum allowable number of lives for each instrument, utilizing knowledge gained from years of instrument usage. Although each design change had its own risk analysis, a cumulative risk analysis was

> completed to understand how risk is affected by all of the changes combined.[220]

121. While the Extended Use Program was limited to certain da Vinci model X/Xi instruments, and found that certain X/Xi instruments are able to be used safely and reliably for a few more than ten uses, Intuitive's testing showed that none of the X/Xi instruments could reliably and safely be used for the number of times third parties claim they can safely reset S/Si instruments. [221] I would expect these findings to apply with equal or greater force to S/Si instruments. Intuitive made improvements to the X/Xi instruments over time such that certain of the X/Xi instruments may have a small number of reliable uses above 10, as Intuitive demonstrated as part of the Extended Lives Program. For example, Intuitive changed a number of components used in X/Xi instruments including the pitch cable, grip cable, and the grips.[222] Since those component changes were not made to S/Si instruments, there is no basis to assume that those instruments would perform reliably over more than 10 uses.

122. In Intuitive's Extended Use Program testing, twelve different X/Xi instrument models and a total of 250 instruments were tested. Life test protocols involving an initial reprocessing cycle, followed by interleaved surgical use cycles (SUCs) and reprocessing cycles, consistent with Intuitive's typical life testing protocols described above.[223] The instruments were put through 14 to 22 SUCs, and at least one instrument of every model suffered failures by SUC

[220] Intuitive-00004692 at Intuitive-00004692.

[221] Intuitive-00290857 at Intuitive-00290859; Oct. 27, 2022 Nickola Goodson Tr. at 222:13–20, 232:18–233:18, 233:19–24; Oct. 6, 2022 Disha Peswani Tr. at 106:8–17, 113:21–114:4, 114:9–18, 115:4–12, 156:2–9; Intuitive-00004692; Intuitive-00004685; Intuitive-00552529; Intuitive-00552530; Intuitive-00552535.

[222] Oct. 6, 2022 Disha Peswani Tr. at 116:2–13.

[223] See *supra* §§ V.A-B.

22. Further, a total of 70 failures were observed from the 250 units. 52 of those instruments failed as a result of cable drivetrain stretch/fatigue/yield.[224]

123. Using Weibull analysis, Intuitive engineers showed that the extended life test results provided evidence that the instruments were reliable for between 12 and 18 uses. None of them were shown to meet reliability standards for the number of uses (19 or 29) that Rebotix claims to have verified.[225]

124. In contrast, Rebotix's life testing did not identify a single failure through 20 life cycles.[226] This stark difference in results cannot be explained by the differences between Intuitive's X/Xi and S/Si EndoWrist instruments and provides further evidence of the inadequacy of the Rebotix life test protocols to simulate surgical usage.

C. <u>Rebotix's Summary of Quality and Reliability Measures and Technical File Review Do Not Support Any Safety and Reliability Claims.</u>

125. [redacted]

[224] Intuitive-00552535.

[225] *See id.*; *see also e.g.*, Rebotix's Responses and Objections to Intuitive's Second Set of Interrogatories, at Interrogatory 3. I note that the spreadsheet summarizing Intuitive's extended life test results indicates that the ProGrasp instrument "Rated USE life Qualified" is 20 uses. *See* Intuitive-00552535. However, the original test document (862214-04R) and the Extended Lives White Paper both state that the verified number of uses is 18. *See* Intuitive-00551503; Intuitive-00004692.

[226] *See* REBOTIX170053.

[227] Restore-00060361.

[228] Restore-00060362.

[229] Restore-00060365.

[redacted]

126. I also understand that during the period Restore was utilizing the Interceptor to bypass Intuitive's usage counter, Restore did not perform any independent testing to validate the use of the EndoWrist instruments for uses beyond the usage limit prescribed by Intuitive but rather "just relied on . . . Rebotix."[230]

127. [redacted]

128. I understand that the material provided to SIS by Rebotix on Rebotix's risk management activities and testing was limited to the "Summary of Quality and Reliability

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[230] May 6, 2021 Kevin May Tr. at 129:3-130:21

[redacted]

Measures" document.[232] SIS did no independent testing of the EndoWrist instrument reset process and instead relied on Rebotix's testing.[233]

129. The Summary of Quality and Reliability Measures document does not demonstrate the safety and reliability of Rebotix's resetting process, providing only a high-level listing of the processes, standards, and tests that were purportedly applied to the development of the Rebotix repair process. Insufficient information is provided to determine if the devices are actually safe and reliable. For example, the section titled "Risk Management" states that a "A detailed FMEA (Failure Modes and Effects Analysis) was performed covering the service process."[234] No information is provided about the process used to develop the FMEA, and if the process was inadequate or the FMEA was incomplete then the results do not establish a suitable level of safety or reliability.

130. Similarly, the "RELIABILITY/PERFORMANCE TEST SUMMARY" section states that new EndoWrist instruments were characterized to determine functional properties (*See* Figure 13), and then repaired instruments were subjected to formal life testing to establish reliability:

[232] *See* Nov. 1, 2022 Greg Posdal 30(b)(6) Tr. at 25:7-25; *id.* at 27:15-20; Def.'s Ex. 136, SIS095115-095139 at SIS095126-095139.

[233] Nov. 1, 2022 Greg Posdal 30(b)(6) Tr. at 22:24-23:2; *id.* at 23:23-24:1; *id.* at 25:1-6; *id.* at 29:6-11; *id.* at 30:8-13; *id*. at 32:4-6; *id.* at 49:23-50:3.

[234] Def.'s Ex. 136, SIS095115-095139 at SIS095132.

Initially, a quantity of each representative model was characterized by their mechanical and functional properties. New OEM instruments were analyzed to provide baseline statistics and information. Examples of such statistics include, but were not limited to:

- Tool end range of motion
- Tool end functional performance (e.g. grasping performance and cutting performance)
- RF energy effectiveness
- Electrical safety testing
- General instrument condition
- Effective communication and use counting on the host system

Figure 13.[235]

> Following the OEM characterization, instruments with one remaining use underwent the repair process. Immediately following the repair process, the instruments were subjected to the same baseline testing in order to establish equivalence. Formal life-testing was then conducted to simulate an additional 10 uses. The life testing subjected the instrument to 10 simulated surgical environments to test each aspect of the individual instrument's functional capabilities.[236]

131. It is not possible to determine from the summary information provided what was included in the testing and evaluation. If the "simulated surgical environments" that were used to test the repaired instruments did not include realistic motions and loading typical of actual surgery, then the test results are inadequate to establish safety and reliability.

132. The same section of the document states "A worst-case analysis was carried out to determine which models should be used during performance and life testing."[237] No information is provided about the criteria used to determine which instruments represent the "worst-case," or even how "worst-case" is defined. The document does not state which set of instrument models were selected. Without such information, it is not possible to determine if the selection process was appropriate and effective.

[235] *Id.* at SIS095137.

[236] *Id.*

[237] Def.'s Ex. 136, SIS095115-095139 at SIS095136.

133. The "RELIABILITY/PERFORMANCE TEST SUMMARY" section also states:

> Following the formal testing described above, a smaller batch of representative models were subjected to over 50 cleaning and sterilization cycles to demonstrate the robust nature of the instrument's design. Similar inspection and testing was carried out on these devices, and, as expected, no indications of material degradation were observed.[238]

Here again, the document does not provide essential information to determine safety and reliability. The process used for "inspection and testing" is not explained in any detail, and it is not specified how "material degradation" was assessed.

134. The document also lists over two dozen industry standards, and states "The following list of standards was considered and applied to the development process…" and "Tests were conducted with devices serviced to demonstrate compliance to the following standards…"[239] Once again, no information is provided about how these standards were "applied to the development process" or how the tests were conducted. Without this information, it is not possible to determine if they support an assessment of safety and reliability.

VII. Intuitive's Efforts to Create a Refurbishment Program Do Not Prove the Safety or Reliability of EndoWrists Reset by Third Parties.

135. I understand that between 2016 and 2020, Intuitive considered starting an EndoWrist refurbishment program for X and Xi instruments.[240] Plaintiff's experts appear to assume Intuitive's consideration of such a refurbishment program constitutes evidence that third-party EndoWrist "reset" offerings are safe and reliable.[241] I disagree.

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[238] Def.'s Ex. 136, SIS095115-095139 at SIS095138.

[239] Def.'s Ex. 136, SIS095115-095139 at SIS095132-135.

[240] Oct. 27, 2022 Goodson Tr. at 70:11–72:20.

[241] *See* Lamb Rep. ¶¶ 60–63, 137–39; Bero Rep. § VII.

136. Intuitive ultimately did not implement a refurbishment program because it would have needed to demonstrate the reliability of the refurbished instruments and it determined that the cost associated with part replacements necessary to achieve that reliability became "cost prohibitive."[242] For example, Intuitive replaced the EndoWrist cables during its refurbished instrument testing process but still observed broken cables during life testing.[243] In other words, Intuitive concluded that safely and reliably refurbishing EndoWrist instruments required replacing components of the instruments, not simply sharpening them and manually adjusting cables.

137. The outcome of Intuitive's refurbishment project testing therefore actually supports my conclusion that the Rebotix process was inadequate, rather than suggesting that the third-party EndoWrist reset processes are safe and reliable.

VIII. The FDA's Recent Clearance of the Iconocare Process Does Not Prove the Safety and Reliability of Other Resetting Processes.

A. The Iconocare Remanufacturing Process

138. Iconocare submitted a 510(k) premarket notification submission for the Iconocare Process on February 16, 2021.[244] The submission included a number of supporting documents.[245]

139. Six months later, following numerous email communications and meetings,[246] Iconocare formally supplemented its 510(k) application, providing additional data and information, as well as evidence of revisions to the Iconocare Process reflecting comments and

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[242] *Id.* at 73:6–13.

[243] *See, e.g.*, Intuitive-00626429 at Intuitive-00626431–32.

[244] Restore-00086907.

[245] Restore-00086957–Restore-00087398.

[246] *See, e.g.*, Restore-00095403.

concerns from the FDA.[247] Iconocare continued to provide additional information to the FDA over the following months.[248]

140. Ultimately, on September 30, 2022, the FDA determined that an S/Si 8mm Monopolar Curved Scissor instrument remanufactured to be reset one time with ten additional lives (for a total of up to 19) using the Iconocare Process was "substantially equivalent" to previously-cleared predicate devices, and therefore cleared the device for marketing in the United States.[249] The FDA did not clear Iconocare to remanufacture any other Intuitive instruments or to remanufacture the S/Si 8mm Monopolar Curved Scissors more than once.[250]

B. The Rebotix Process and Iconocare Process Are Materially Different.

141. It is my opinion that there are significant differences between the Rebotix Process for remanufacturing S/Si EndoWrist instruments and the Iconocare Process for remanufacturing the S/Si 8mm Monopolar Curved Scissor EndoWrist, and these differences are likely to have a material impact on instrument reliability and patient safety. Some examples are listed below.

142. The Iconocare Process and Rebotix Process use different methods for altering the use counter in the instrument. An overview of the Rebotix Process for circumventing the usage counter on EndoWrist instruments was provided above in Section VI.

[247] *See* Restore-00087401–Restore-00089708.

[248] *See, e.g.*, Restore-00106446; Restore-00132582; Restore-00109056.

[249] Restore-00099137.

[250] Restore-00099137; Restore-00099139; *see also* AHP000528 (FDA Major Deficiency List stating "[p]lease revise the statements to clearly indicate that the reprocessing instructions only apply to Monopolar Curved Scissors instrument and not to all da Vinci EndoWrist instruments.").

[redacted]

144. [redacted][253]

145. [redacted]

[redacted]

[redacted][254];

[251] Restore-00089490 at Restore-00089495.

[252] Restore-00089490 at Restore-00089495

[253] *See* Restore-00089490 at Restore-00089495, –98.

[254] Restore-00001538 at Restore-00001562; Restore-00089490 at Restore-00089495 (Iconocare Process pt. 7.3.5.1.8).

[redacted]

146. While each of these steps will generate particulate debris, methods for thoroughly removing this debris are not provided in the Rebotix Process.[258]

147. [redacted]

[255] Restore-00001538 at Restore-00001565; Restore-00089490 at Restore-00089495 (Iconocare Process pt. 7.3.5.2.2).

[256] Restore-00001538 at Restore-00001565; Restore-00089490 at Restore-00089495 (Iconocare Process pt. 7.3.5.2.3).

[257] Restore-00001538 at Restore-00001565; Restore-00089490 at Restore-00089496 (Iconocare Process pt. 7.3.5.3.2).

[258] *Supra* § VI.A.

[259] Restore-00089490 at Restore-00089497–98.

[260] *Id*.

[redacted]

261 Restore-00089490 at Restore-00089497.

262 Restore-00089490 at Restore-00089497–98

148. [redacted] Corrosion is a particularly significant issue for EndoWrist Instruments. As explained in Section IV.B above, "The corrosion that results from reprocessing is well-known to degrade wire rope drives." Corrosion accelerates wire-rope deterioration by reducing rope metallic area, limiting flexibility, and creating uneven wire surfaces that may cause internal damage to the rope and other equipment.[264] While not all corrosion is externally visible in these instruments, inspection can detect external signs of degradation and serves to enhance instrument safety. The Rebotix Process, by comparison, has an insufficient visual inspection.[265]

149. [redacted]

[263] Restore-00089490 at Restore-00089493.

[264] *Id*. (quoting U.S. Navy Wire-Rope Handbook, Vol. 1, p. 3-15).

[265] *See, e.g.*, REBOTIX162404 at REBOTIX162413; REBOTIX162421–22.

[266] Restore-00089490 at Restore-00089492.

[redacted]

150. [redacted] Thorough documentation is essential for ensuring safety and reliability of medical device manufacturing practices.[270]

C. <u>The Rebotix Process and Iconocare Process are Supported by Materially Different Risk Management and Life Testing Data.</u>

151. It is my opinion that there are significant differences between the risk management and life testing data Rebotix had access to in connection with the Rebotix Process

[267] Restore-00089490 at Restore-00089492.

[268] Restore-00089490 at Restore-00089490.

[269] *Id*. at Restore-00089491.

[270] *See* 21 C.F.R. §§ 820.180 *et seq.*; ISO 13485:2016 § 4.2.

and the risk management and life data submitted to the FDA for the Iconocare Process. Some examples are listed below.

152. [redacted]

153. [redacted]

[271] Restore-00086907 at Restore-00086909–10.

[272] *See, e.g.*, Restore-00087401 at Restore-00087464.

[273] Restore-00086907 at Restore-00086912.

[redacted]

154. [redacted]

[274] Restore-00086907 at Restore-00086912.

[275] Restore-00087861.

[276] *Id.* at Restore-00087868–69.

[277] [redacted]

[278] Restore-00087861 at Restore-00087869.

[redacted]

Figure 19.[279]

[redacted]

156. Such testing provides quantitative information for assessing the reliability of the remanufactured instruments, which is absent from the limited information available in connection with the Rebotix Process.

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[279] Restore-00087861 at Restore-00087869

[280] Restore-00086959.

[281] *Id.* at Restore-00086965.

D. Significantly Greater Safety Risks Are Created by Resetting an EndoWrist Usage Counter Multiple Times.

157. Plaintiff's experts have claimed that "EndoWrist instruments repaired or reprocessed by third parties such as SIS were equally as safe as" new EndoWrists.[282] I am not aware of any support for that claim. As discussed above (*supra* § VI.B), Rebotix's inadequate and flawed life testing only tested EndoWrists through 20 life cycles. While *Restore* has claimed that EndoWrists could be reset anywhere from once to eight times, it has never had any evidence supporting that claim. Similarly, while SIS claimed that it could reset EndoWrists five times,[283] it never had any evidence supporting that claim. To the contrary, and as also discussed above (*supra* § VI.C), the only testing documentation Restore ever had access to was a "Technical File Review" offering a brief summary of Rebotix's life testing that only encompassed one reset and the only testing documentation SIS had access to was a "Summary of Quality and Reliability Measures," which offers only a high-level summary of testing that Rebotix purportedly performed.

158. [redacted][285]

[282] Lamb Rep. ¶ 132.

[283] Oct. 27, 2022 Keith Johnson 30(b)(6) Tr. at 77:6–78:15.

[284] *See* Restore-00090136 at -162–63 ("7.2.4.1. Unrepairable Items: Any model (or instrument version) not on the Approved Model List or in the Recall List are not eligible for repair. Previously refurbished instruments are not eligible for repair. All ineligible repairs are moved to a quarantine area pending disposition by management."); *see also* Restore-00087134.

[285] [redacted]

159. It is my opinion that resetting an instrument's usage counter multiple times, as the Restore Process contemplated, has a significantly greater impact on instrument reliability and patient safety than resetting an instrument's usage counter just once under the Iconocare Process.

160. As explained above, data and analyses show that mechanical failures represent a large portion of all failures observed in EndoWrist instruments, and that continued use of EndoWrists beyond their originally specified number of uses increases the risk of instrument failure.[286]

161. The data demonstrates that instruments wear out and show increased failure rates with increased usage.[287] For example, the Rebotix EndoWrist MDR Report notes that almost half of all MDRs indicate something broken, including broken grips, wires, clevis, conductor caps, and blade tips.[288] For one instrument, 17 of 52 observed instrument failures involved the cable drives, e.g., "grip cable derailed at distal idler" and "pitch cable broken at distal clevis."[289] The same pattern of a large fraction of the failure reports mentioning cable issues is observed for many of the instruments analyzed.[290] More of these failures are observed in instruments that are later in their original ten-use life cycle than those at the beginning of that cycle.[291]

[redacted]

[286] *Supra*, ¶¶ 107–111.

[287] *Supra*, ¶ 111.

[288] *Supra*, ¶¶ 109–110.

[289] *Id.*

[290] *Id.*

[291] *Supra*, ¶ 111.

162. The above evidence shows that EndoWrist instrument failure rates increase with the number of procedures where they are used. This implies that the reliability of these instruments will continue to decrease as they are remanufactured for use beyond 20 lives.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 18th day of January, 2023, at Brewster, Massachusetts.

Robert D. Howe, Ph.D.
January 18, 2023

Appendix A

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Employment

1997-present **Abbott and James Lawrence Professor of Engineering,** Harvard Paulson School of Engineering and Applied Sciences. Conducting research in robotic manipulation, tactile sensing, surgical robotics, medical image processing, human-machine interfaces, and biomechanics; teaching graduate and undergraduate engineering courses.

1994-1997 **Associate Professor of Mechanical Engineering,** Harvard University

1990-1994 **Assistant Professor of Mechanical Engineering,** Harvard University

1984-1990 **Research Assistant,** Mechanical Engineering Department, Stanford University

1981-1983 **Research Physicist,** High Temperature Gasdynamics Laboratory, Stanford University. Developed optical and electronic research instruments, conducted flow visualization and combustion diagnostics experiments.

1979-1981 **Electronics Engineer,** Kratos Display Systems, Los Gatos, CA. Designed analog and digital electronics.

Secondary Academic Appointments

Founding Co-Director, Harvard MS/MBA Program (Dual Master's degree program between Harvard's Business and Engineering Schools), 2018-present

Area Dean for Bioengineering (equivalent to department chair), Harvard Paulson School of Engineering and Applied Sciences, 2010-2011, 2012-2016

Associate Dean for Academic Programs (Chief Academic Officer), Harvard School of Engineering and Applied Sciences, 2008-2011

Adjunct Professor, Department of Biomedical Engineering, Tufts University, 2007 - present

Member of the Core Faculty, Harvard-MIT Division of Health Sciences and Technology, 1999 - present

Thinker in Residence, Deakin University, Australia, Fall 2015

Visiting Professor, Singapore University of Technology and Design, Spring 2012

Visiting Scientist, INRIA Sophia-Antipolis, France, Spring 2004

Visiting Scholar, Mechanical Engineering Department, Stanford University, Spring 1999

Visiting Scientist, Artificial Intelligence Laboratory, Massachusetts Institute of Technology, Fall 1998

Education

1990 Doctor of Philosophy in Mechanical Engineering, Stanford University.

1985 Master of Science in Mechanical Engineering, Stanford University.

1979 Bachelor of Arts in Physics, Reed College.

Selected Professional Awards and Honors

Fellow, Institute of Electrical and Electronics Engineers (IEEE), 2012.

Fellow, American Institute for Medical and Biological Engineering (AIMBE), 2007.

I.S. Ravdin Lecture, American College of Surgeons 97th Annual Clinical Congress, San Francisco, 2011.

Keynote address, 5th International Conference on Functional Imaging and Modeling of the Heart, Nice, France, 2009.

Keynote address, SPIE Medical Imaging Conference, San Diego, 2008.

Keynote address, EuroHaptics Conference, Munich, 2004.

Whitaker Foundation Biomedical Engineering Research Grant (Career development award), 1995.

National Science Foundation Young Investigator Award, 1993.

Selected Professional Service

Journals

Associate Editor, *International Journal of Robotics Research*, 2019-present

Advisory Board, *Science Robotics*, 2017-present.

Editorial Board, *Medical Image Analysis*, 2008-present.

Management Committee, Founding member, *IEEE Transactions on Haptics,* 2007-2013.

Associate editor, *IEEE Transactions on Robotics and Automation,* 1994-1998.

Conferences and workshops

Co-organizer, Workshop on Closing the Loop on Upper-Limb Assistive Device Design, Sensing, Control, & Clinical Practice, IEEE RAS/EMBS International Conference on Biomedical Robotics & Biomechatronics (BioRob), August 21, 2022, Seoul.

Co-organizer, Tutorial on Jamming in Robotics: From Fundamental Building Blocks to Robotic Applications, IEEE International Conference on Robotics and Automation (ICRA), May 23, 2022, Philadelphia.

Program Co-Chair, International Conference on Medical Image Computing and Computer-Assisted Intervention (MICCAI), 2014; Program Committee, 1998, 2000, 2002-2007, 2016, 2017.

Program Committee, Intl. Symposium on Medical Robotics and Computer Assisted Surgery, 1994, 1995, 1997.

Program Committee, Intl. Conference on Functional Imaging and Modeling of the Heart, 2009, 2011, 2013.

Area Chair, Robotics: Science and Systems Conference (RSS), Philadelphia, August 16th-19th, 2006 and Cambridge, July 12-16, 2017; program committee member 2007, 2018.

Co-Chair, International Program Committee, First IEEE World Haptics Conference (First Joint Eurohaptics Conference and Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems), Pisa, Italy, 18-20 March, 2005.

Chair and Organizer, Annual Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems, Atlanta, Nov. 1996; Dallas, Nov. 1997; and Anaheim, 1998 (with Susan J. Lederman); program committee member, 1999-2008.

Program Committee, IEEE Intl. Conference on Robotics and Automation, 1994, 1997, 1998, 2005.

Program Committee, IEEE/RSJ Intl. Conference on Intelligent Robots and Systems (IROS), 2004.

Program Committee, Second Intl. Symposium on Medical Simulation, 2004.

Program Committee, Intl. Symposium on Surgery Simulation and Soft Tissue Modeling (IS4TM 2003), Juan-Les-Pins, France, June 2003.

Program Committee, IEEE Intl. Conference on Systems, Man, and Cybernetics, Tokyo, 1999.

Program Committee, Frontiers of Engineering Symposium, National Academy of Engineering, Irvine, CA, Nov. 1998.

Academic Visiting and Advisory Committees

Advisory Board, Robotics Engineering (RBE) Program, Worcester Polytechnic Institute, 2018-present.

Advisory Board. Department of Mechanical Engineering and Applied Mechanics, University of Pennsylvania, 2015-present.

Visiting Committee, Department of Mechanical Engineering, Stanford University, 2015-16.

Advisory Board, Centre for Autonomous Systems, University of Technology, Sydney, Australia, 2016-2020.

Visiting Committee, Department of Mechanical and Process Engineering (Maschinenbau und Verfahrenstechnik), Eidgenössische Technische Hochschule (ETH) Zürich, 2006-2007.

Government Panels

Strategic Advisory Board, Engineering and Physical Sciences Research Council – United Kingdom Network for Robotics and Autonomous Systems (EPSRC UK-RAS), 2015 – 2020.

Funding Review Panel Member, National Science Foundation, 1994, 2000, 2010, 2014, 2017, 2021, 2022.

DARPA Information Science and Technology (ISAT) Study Group, 2008-2011.

Study section, National Institutes of Health, 2003, 2005.

PUBLICATIONS

Journal Articles

104. Moradi Dalvand M, Nahavandi S, Howe RD, "General Forward Kinematics for Tendon-Driven Continuum Robots," *IEEE Access* **10**:60330-40, 2022
103. Teeple CB, Aktaş B, Yuen MC, Kim GR, Howe RD, Wood RJ, "Controlling Palm-Object Interactions Via Friction for Enhanced In-Hand Manipulation," *IEEE Robotics and Automation Letters* **7**(2):2258-65, 2022. Also presented at the IEEE International Conference on Robotics and Automation, Philadelphia, 2022.
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91. Gaffney LP, Loschak PM, Howe RD, "A Deployable Transseptal Brace for Stabilizing Cardiac Catheters," *Journal of Mechanical Design* **140**(7):075003, 2018.
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Expert Witness Experience: Depositions, Trial Testimony, and IPR Declarations
Robert D. Howe
January 2023

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No. 5:19-cv-55-TKW-MJF, Northern District of Florida
Testified at deposition for Intuitive Surgical (defendant, represented by Skadden, Arps, Slate, Meagher & Flom LLP). October 2021.

Rebotix Repair LLC v. Intuitive Surgical, Inc.
No. 8:20-cv-2274-T-33TGW, Middle District of Florida
Testified at deposition for Intuitive Surgical (defendant, represented by Skadden, Arps, Slate, Meagher & Flom LLP). October 2021.

Rex Medical, L.P. v. Intuitive Surgical, Inc.
No. 19-cv-00005-MN, District of Delaware
Testified at deposition and trial for Intuitive Surgical (defendant, represented by Winston & Strawn). Tried October 2022.

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No. 17-871-LPS-CJB, District of Delaware
Testified at ITC evidentiary hearing for Intuitive Surgical (defendant, represented by Keker, Van Nest & Peters). Feb. 2021.

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No. 2:17-cv-00572-JRG, Eastern District of Texas
Testified at deposition for Immersion Corporation (plaintiff, represented by Morrison & Foerster). 2018-2019.

Immersion Corporation v. Motorola Mobility LLC and Motorola Mobility Holdings LLC
No. 17-1081-RGA, District of Delaware
Testified at deposition for Immersion Corporation (plaintiff, represented by Morrison & Foerster). 2018-2019.

Zenimax Media Inc. and Id Software LLC v. Oculus VR LLC, Facebook Inc., et al.
No. 3:14-CV-01849, Northern District of Texas
Testified at deposition and trial for Oculus VR LLC, Facebook Inc., et al. (defendants, represented by Cooley), tried January 2017.

Appendix B

List of Materials Considered

<u>Produced Documents</u>
(*In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC and *Surgical Instrument Service Co. v. Intuitive Surgical, Inc.*, Case 3:21-cv-03496-VC):

- Intuitive-00004685
- Intuitive-00004692
- Intuitive-00008958
- Intuitive-00010744
- Intuitive-00010745
- Intuitive-00027876
- Intuitive-00043879
- Intuitive-00104966
- Intuitive-00223998
- Intuitive-00290857
- Intuitive-00369329
- Intuitive-00477154
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- Intuitive-00705431
- Intuitive-00705438
- Intuitive-00705453
- Intuitive-00784474
- Intuitive-01085065
- Intuitive-01085533

Produced Documents (Restore/Rebotix):

- ACG000006
- AHP000369
- AHP000373
- AHP000404
- AHP000525
- AHP000527
- AHP000658
- AHP000706
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- AHP000729
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- Restore-00132592

Deposition Transcripts and Exhibits
(*In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC and *Surgical Instrument Service Co. v. Intuitive Surgical, Inc.*, Case 3:21-cv-03496-VC):

- Duque, Grant 30(b)(6) (Nov. 8, 2022) and Exhibits
- Goodson, Nickola (Oct. 27, 2022) and Exhibits
- Hamilton, Stan (Nov. 4, 2022) and Exhibits
- Johnson, Keith (Oct. 27, 2022) (individual testimony) and Exhibits
- Johnson, Keith 30(b)(6) (Oct. 27, 2022) and Exhibits
- May, Kevin (Nov. 3, 2022) and Exhibits
- Parker, Clifton (Oct. 25, 2022) and Exhibits
- Peswani, Disha (Oct. 6, 2022) and Exhibits
- Posdal, Greg (Nov. 1, 2022) (individual testimony) and Exhibits
- Posdal, Greg 30(b)(6) (Nov. 1, 2022) and Exhibits
- Somayaji, Sharathchandra (Nov. 4, 2022) and Exhibits

Deposition Transcripts and Exhibits
(*Restore Robotics LLC v. Intuitive Surgical, Inc.*, Case No. 5:19-cv-55-TKW-MJF):

- Gordon, West (May 13, 2021) and Exhibits
- May, Kevin (May 6, 2021) and Exhibits
- May, Kevin (June 8, 2021) and Exhibits
- Parker, Clifton (May 4, 2021) and Exhibits
- Vautrot, Mills (May 11, 2021) and Exhibits

Expert Reports
(*In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC)

- Expert Report of Professor Einer Elhauge (Dec. 1, 2022)
- Expert Report of Dr. Eugene Rubach (Dec. 1, 2022)
- Expert Report of Kimberly A. Trautman, MS (Dec. 1, 2022)

Expert Reports
(*Surgical Instrument Service Co. v. Intuitive Surgical, Inc.*, Case 3:21-cv-03496-VC)

- Expert Report of Richard F. Bero (Dec. 2, 2022)

- Expert Report of Dr. Russel L. Lamb (Dec. 2, 2022)
- Expert Report of Amandeep Mahal, MD (Dec. 1, 2022)
- Expert Report of Philip J. Philips (Dec. 2, 2022)

Court Documents
(*In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC)

- Consolidated Class Action Complaint (ECF. No 52)
- Defendant Intuitive Surgical, Inc,'s Answer and Affirmative Defense (ECF 74)
- Plaintiff Franciscan Alliance, Inc.'s Amended Objections and Responses to Defendant's Second Set of Interrogatories to Plaintiffs (Sept. 30, 2022)
- Plaintiff Larkin's Amended Objections and Responses to Defendant's Second Set of Interrogatories to Larkin (Sept. 30, 2022)
- Plaintiff Valley Medical Center's Amended Objections and Responses to Defendant's Second Set of Interrogatories to Plaintiffs (Sept. 30, 2022)
- Plaintiff Franciscan Alliance, Inc.'s Objections and Responses to Defendant's Requests for Admissions to Plaintiff (Nov. 16, 2022)
- Plaintiff Larkin Community Hospital's Objections and Responses to Defendant's Requests for Admissions to Plaintiff (Nov. 16, 2022)
- Plaintiff Valley Medical Center's Objections and Responses to Defendant's Requests for Admissions to Plaintiff (Nov. 16, 2022)

Court Documents
(*Surgical Instrument Service Co. v. Intuitive Surgical, Inc.*, Case 3:21-cv-03496-VC):

- SIS Complaint (ECF No. 1)
- Defendant Intuitive Surgical, Inc.'s Answer, Affirmative Defenses, and Counterclaims (ECF No. 75)
- Plaintiff Surgical Instrument Service Company, Inc.'s Answers & Objections to Defendant's Interrogatories, Second Set – Nos. 4-18 (Aug. 8, 2022)

Other Materials:

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- August 19, 2021 Conversation with Ron Bair
- da Vinci S and Si Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=d237e175-3fce-3844-863e-37e733afe0d6&groupId=73750789
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https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=b1b9f169-4503-9ea9-6db9-9243c28d5221&groupId=73750789

- Def.'s Ex. 135 (Defendant Intuitive Surgical Inc.'s Notice of Deposition of Plaintiff Surgical Instrument Service Company, Inc. Pursuant to Fed. R. Civ. P. 30(b)(6))
- Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, available at: https://www.fda.gov/media/116573/download
- DS2505 Dallas Semiconductor data sheet, available at: https://datasheets.maximintegrated.com/en/ds/DS2505.pdf
- "Expanding the Reach of Surgery," Medrobotics "Flex" brochure, available at: https://www.easmed.com/main/wp-content/uploads/BROCHURE-Medrobotics-Transanaleasmed.pdf
- Expert Report of Dr. Robert D. Howe (July 26, 2021) (served in *Rebotix*, Case 8:20-cv-02274-VMC-TGW) and materials cited therein
- Expert Report of Dr. Robert D. Howe (Aug. 20, 2021) (served in *Restore*, Civil Case No. 5:19-cv-55-TKW-MJF) and materials cited therein
- Expert Report of Dr. Robert D. Howe (Dec. 2, 2022) (served in *Surgical Instrument Service*, Case 3:21-cv-03496-VC) and materials cited therein
- Supplemental Expert Report of Dr. Robert D. Howe (Dec. 23, 2022) (served in *Restore*, Civil Case No. 5:19-cv-55-TKW-MJF) and materials cited therein
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